EPA Jacket 71355-1

Vol.2

FOR OFFICIAL USE ONLY

FILE SYMBOL
REGISTRATION NO.

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER

Do Not Write Comments, Formula, or Parts of Formula on This Envelope

NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

Pages 2-4*Confidential Statement of Formula may be entitled to confidential treatment*

Material to be added to an e-Jacket/Jacket

Reg. No. 71355-1

1. ☐ **Placement within the e-Jacket/jacket:**
   - ☐ **Default: (chronological, top/newest)**
   - ☐ **Description: (PDF page number, i.e., "before page 45")**

_____

_____

2. ☐ **Send to Data Extraction contractors this material:**
   - ☐ **Newly stamped accepted label**
   - ☐ **Notification**
   - ☐ **New CSF**
   - ☐ **Other:** _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Chris Mixon

Phone: 703-308-8032 **Division:** AD

Date: 12-17-10

Created January 26, 2009

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Sally Hayes,
Scientific & Regulatory
Consultants, Inc.
P.O Box 1014,
Columbia City, IN. 46725

Product Name: Virocid
EPA Reg. No.: 71355-1
Notification Date: July 30, 2010
Receipt Date: August 2, 2010
Submission #: 879635

Dear Ms. Hayes,

The following amendment, submitted in connection with registration under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended is acceptable with comments.

Proposed Amendment

- Add new claims for human influenza A virus (H1N1).
- Upgrade label first aid statement, precautionary statements and storage and disposal language.
- Add data previously rejected to support organisms listed below.

Human Influenza A (H1N1) (ATCC VR-1469)
Swine Influenza A virus (H1N1) (ATCC VR-333)
Campylobacter jejuni (ATCC 33560)
Corynebacterium pseudotuberculosis (ATCC 19410)
Avibacterium (Haemophilus) paragallinarum (ATCC 29975)
Klebsiella pneumonia (ATCC 13883)
Listeria monocytogenes (ATCC 19115)
Mycoplasma gallisepticum (ATCC 19610)
Mycoplasma synoviae (ATCC 25204)
Ornithobacterium rhinotracheale (ATCC 51463)
Pasteurella multocida (ATCC 6529)
Salmonella enteritidis (ATCC 13076)
Fusarium dimerum (ATCC 16553)
Penicillium expansum (ATCC 7861)
Bordetella avium (ATCC 35086)
Salmonella enterica (pullorum) (ATCC 9120)

Conclusions:

- The CSF dated 09/228/10, for the basic formulation is acceptable.
- Please see the attached efficacy review.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Velma Noble PM Team 31 at (703) 308-6233.

Sincerely,

Velma Noble,
Product Manager, Team 31
Regulatory Management Branch
Antimicrobials Division (7510P)

Enclosure: Stamped Label

VIROCID

CONCENTRATED BROAD SPECTRUM DISINFECTANT

Active Ingredients:

ALKYL *DIMETHYL BENZYL AMMONIUM CHLORIDE *(50% C_{14}; 40% C_{12}; 10% C_{16})	17.060%
DIDECYL DIMETHYL AMMONIUM CHLORIDE	7.800%
GLUTARALDEHYDE	10.725%
Other Ingredients:	64.415%
Total	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

VIROCID is effective against:

BACTERIA	DILUTION
Salmonella ~~Choleraesuis (ATCC 10708)~~ enterica (formerly *S. choleraesuis*)*	1:400
*Staphylococcus aureus ~~(ATCC 6538)~~**	1:400
*Pseudomonas aeruginosa ~~(ATCC 15442)~~**	1:400
*Campylobacter jejuni**	1:400
*Corynebacterium pseudotuberculosis**	1:400
Avibacterium paragallinarum (formerly *H. paragallinarum*)*	1:400
*Klebsiella pneumoniae**	1:400
*Listeria monocytogenes**	1:400
*Mycoplasma gallisepticum**	1:400
*Mycoplasma synoviae**	1:400
*Ornithobacterium rhinotracheale**	1:400
Salmonella enterica (formerly *S. enteritidis*)*	1:400
*Mycoplasma hyopneumoniae***	1:400
*Streptococcus suis**	1:400
Salmonella enterica ~~choleraesuis, serotype typhisuis (ATCC 8321)~~ (formerly *S. typhisuis*)**	1:400
*Escherichia coli**	1:400
*Bordetella avium**	1:256
Salmonella enterica (formerly *S. pullorum*)**	1:256
FUNGUS (on environmental surfaces)	
*Fusarium dimerum**	1:400
*Penicillium expansum**	1:400
Trichophyton mentagrophytes	1:400
VIRUS (on environmental surfaces)	
Porcine circovirus, type II [PCV, PT-1 cell]*	1:200
Pseudorabies [American BioResearch Laboratories]*	1:400
Porcine Respiratory and Reproductive Syndrome [Arko Laboratories]*	1:400
Avian Reovirus [Spafas Strain]*	1:256
Marek's Disease [Spafas Strain]*	1:400
Newcastle Disease [Spafas Strain]*	1:400
Avian Influenza [Turkey/Wis/66 strain-H9N2]*	1:400
Human Influenza A (H1N1)*	1:400
Swine Influenza A (H1N1)*	1:400
Avian Infectious Laryngotracheitis [Charles River Laboratories]*	1:400
Infectious Bursal Disease [Spafas Strain 2512]*	1:400
Algae and slime forming bacteria in recirculating water cooling systems and evaporative condensers	**25-50 ppm**

*in the presence of 400 ppm AOAC synthetic hard water and 5% soil load
**in the presence of 400 ppm AOAC synthetic hard water and 25% soil load

Note: Bracketed[ ]information is optional text. Text separated by a comma(,)denotes--and/or-options. {Bracketed Text}is for administrative purposes only and will not appear on the printed label.

FIRST AID ~~STATEMENTS~~	
IF IN EYES	• Hold ~~eyelids~~ open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing ~~eyes~~. • Call a poison control center or doctor for treatment advice.
IF ON SKIN ~~OR CLOTHING~~	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything ~~by mouth~~ to an unconscious person.
IF INHALED	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
[For emergency information on [product, use, etc.[, call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222.] **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Have a product container or label with you when calling the poison control center, doctor, or going for medical treatment.	

APPLICATION:

Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment:

1. Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings)
2. Hatchers, setters, and chick processing facilities
3. Food processing plants [slaughterhouses)
4. Trucks and other vehicles
5. Veterinary hospitals

Sanitizing hatchery rooms, incubators, and hatchers, poultry houses and livestock buildings by fogging. Control of algae and slime forming bacteria in recirculating water cooling systems and evaporative condensers.

DIRECTIONS FOR USE:

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment:

1. Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings):
   For disinfection of hard, non-porous surfaces: stainless, galvanized and painted steel, copper, aluminum, finished wood, vinyl, plastics, glazed tiles, sealed brick walls, aluminum sandwich panels and feeding/drinking equipment:
   A. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
   B. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with the appropriate disinfection solution† by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
   C. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried.
   D. Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and rinse with portable water before reuse.

E. Disinfection of equipment: Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure in the appropriate disinfection solution† for 10 minutes. Allow to air dry.
F. Fresh disinfection solution should be made daily or if visibly soiled.

2. **Hatcheries:**
Remove all animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, carts, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with the appropriate disinfection solution† by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed or dried. Fresh disinfection solution ~~should~~ must be made daily or if visibly soiled.

3. **Food processing plants (including Chicken Processing Facilities):**
Before using this product, all food products and packaging materials must be removed from the room or carefully protected. Thoroughly clean all surfaces with soap or detergent, then rinse with water. Disinfect hard, non-porous surfaces by applying the appropriate disinfection solution† with a coarse spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

4. **Trucks and other vehicles:**
Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the appropriate disinfection solution† to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

5. **Veterinary hospitals:**
For disinfection of the following hard non-porous surfaces: floors, walls, ceilings, counters, cages, feeding/drinking equipment, and handling/restraining equipment. Remove animals and feed from the premises. Thoroughly clean all surfaces with soap or detergent, then rinse with water. Saturate surfaces with the appropriate disinfection solution† by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Immerse all leashes, muzzles, ropes or other types of equipment used to restrain or handle animals as well as shovels, scrapers, and forks used to remove manure and litter. Do not house livestock or employ equipment until surfaces have been absorbed or dried. Thoroughly scrub treated feeding and watering equipment with soap or detergent and rinse with potable water before reuse. Fresh disinfection solution ~~should~~ must be made daily or if visibly soiled.

Preparation table:

Dilution	Preparation Method
1:400	1/3 fluid ounce per gallon of water
1:256	1/2 fluid ounce per gallon of water
1:200	2/3 fluid ounce per gallon of water

† See organism and preparation table to determine the appropriate disinfection solution.

Sanitizing hatchery rooms, incubators and hatchers, poultry houses and livestock buildings by fogging:

A. **Hatchery rooms:**
Close room off so fog is confined to room to be treated. Prepare a stock solution of one (1) part VIROCID to four (4) parts water (25 fluid ounce VIROCID to 100 fluid ounce water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yard. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment.
Note: The generated fog is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after the actual fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt, sleeves, and pants.

B. Incubators and hatchers:
Prepare a stock solution of one (1) part of VIROCID to four (4) parts water. Fog 3 ounces of solution per ~~for~~ 100 cubic feet ~~of this~~ into setters and hatchers immediately after transfer. Repeat daily. Discontinue hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has settled (30-60 minutes after fogging is completed). To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog.
It is also satisfactory to fog setters and hatchers with a 1:1000 solution of VIROCID. If this is done, fog for 30-90 seconds once per hour or once every two hours.

C. Poultry houses and livestock buildings:
After the house has been depopulated and cleaned as in 1. A to F under "Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment", double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as tight as possible.
Prepare a stock solution of one (1) part VIROCID to four (4) parts water (25 fluid ounce VIROCID to 100 fluid ounce water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yard. Place the fogger ~~itself may be placed~~ just inside the door of the building to be treated, or insert ~~the~~ nozzle of the fogger ~~may be inserted~~ through a suitable opening in the door or building. The opening must ~~should~~ be just large enough to accommodate the nozzle.
After fogging, the building must ~~should~~ be kept closed for twenty-four hours. After twenty-four hours, ~~the fog should have settled and~~ open the house ~~can now be opened~~ and aired~~. The house should be opened~~ for a minimum of twenty-four hours before it is repopulated with poultry or livestock.
Note: The generated fog is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completed settled, normally 1-4 hours after the actual fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt, sleeves and pants.
If feeders and waterers were not removed from the premise during treatment, or were not adequately covered to prevent contact with treatment, they must ~~should~~ be washed with detergent and water before use for poultry or livestock.

Control of algae and slime forming bacteria in recirculating water cooling systems and evaporative condensers:

A. VIROCID must ~~should~~ be added in the system directly at a point where uniform mixing and even distribution will occur. Do ~~and~~ not mix~~ed~~ with any other chemicals or additives.~~; it should be added~~
B. Severely fouled systems must ~~should~~ be chemically and/or manually cleaned before adding VIROCID treatment. If algae/slime growth is absent or minimal, proceed with the initial dose.
C. Initial Dose: 2.5 fluid ounces of VIROCID per 100 gallons of water (50 ppm) in the system. Repeat treatment until algae/slime growth is controlled.
Maintenance Dose: After algae control is evident/achieved, apply 1.25 fluid ounces of VIROCID per 100 gallons of water (25 ppm) in the system every 7 days (weekly). Repeat treatment as needed to maintain algae/slime control.

STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal
Storage: Store in a cool, dry place in tightly closed container away from children. Avoid temperatures below 23°F and above 113°F.
Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance.
Container Disposal: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. *{Insert applicable triple rinse instruction for container size below}* Offer for recycling if available. ~~Triple rinse. Then offer for recycling or puncture and dispose in a sanitary landfill. Disposal by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.~~

(For containers equal to or less than 5 gallons)
Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.
(For containers greater than 5 gallons)
Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container over on its end and tip it back and forth several times. Empty rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

PRECAUTIONARY STATEMENTS:

Hazards to humans and domestic animals
DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if absorbed through ~~the~~ skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves. Harmful if inhaled. Avoid breathing vapor. Harmful if swallowed. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.
Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, ~~or~~ using tobacco, or using the toilet. ~~Remove contaminated clothing and wash before reuse.~~ Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS:

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact our State Water Board or Regional Office of the EPA.

LIMITED WARRANTY AND DISCLAIMER:
The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is a reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warnings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be sotely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warnings or cautions. Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, whether or not such liability is based in the contract, negligence, strict liability in tort of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.

EPA Reg. No. 71355-1 EPA Est. No. 71355-BEL-001
Batch No: See top/bottom
Expiry Date: See top/bottom
Net Contents: See top/bottom

(net contents will appear on front panel; registration numbers, batch no. and expiry date may appear on any panel)

CID LINES®
INNOVATIVE HYGIENE SOLUTIONS

Produced by :
CID LINES NV/SA
Waterpoortstraat 2 – B 8900 IEPER
BELGIUM – EUROPE
Phone : 011 32 57 217877
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www.cidlines.com - info@cidlines.com

Note: Bracketed[ ]information is optional text. Text separated by a comma(,)denotes–and/or-options. (Bracketed Text)is for administrative purposes only and will not appear on the printed label.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

September 27, 2010

DP BARCODE:	D381153
MRID :	
SUBJECT:	Virocid
REG. NO. OR FILE SYMBOL:	71355-1
DOCUMENT TYPE:	Product Chemistry Review
Manufacturing-use [] OR	End-use Product [X]
INGREDIENTS (PC Codes)	n-Alkyl (60% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride (069104); Didecyl dimethyl ammonium chloride (069149); Glutaraldehyde (043901)
CAS number:	68424-85-1, 7173-51-5, 111-30-8
TEST LAB:	
SUBMITTER:	CID LINES® NV/SA
GUIDELINE:	
COMMODITIES:	Formulation
REVIEWER:	Juan F. Negrón
ORGANIZATION:	AD
APPROVER:	Karen P. Hicks
APPROVED DATE:	09/30/10
COMMENT:	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency Office of Pesticide Programs

Antimicrobials Division (AD)

September 27, 2010

MEMORANDUM

Subject:	Product Chemistry Review for EPA Reg # 71355-1.
From:	Juan F. Negrón, Chemist Product Science Branch, CT Team Antimicrobials Division (7510P)
Thru:	Karen P. Hicks, CT Team Leader Product Science Branch Antimicrobials Division (7510P)
To:	Velma Noble / Cletis Mixon PM Team 31
APPLICANT:	CID LINES® NV/SA
Action code:	A570
Due date:	12/23/10

Product Formulation from label
Active Ingredient(s)

	% by wt.
n-Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride	17.060
Didecyl dimethyl ammonium chloride	7.800
Glutaraldehyde	10.725

BACKGROUND:

On behalf of the registrant, CID LINES® NV/SA, the consultant, SRC Scientific & Regulatory, submitted an amendment to update the label and to update change in ownership of the registered active ingredient, glutaraldehyde. [redacted] is now under the ownership of [redacted] requiring a change in the EPA registered active number from [redacted] to [redacted]. In addition, the [redacted] listed in column 13 was corrected to reflect the total product weight as 100% by weight. The Product Chemistry Reviewer has received the following documents:

- A letter, dated 07/30/10 MRID #481742-00.
- A label dated 07/30/10 (by the company).
- Application for pesticide amendment, dated 08/13/10.
- Confidential Statements of Formula (CSFs), dated 06/10/1998, & 07/30/10, for the basic formulation.

FINDINGS:

1. The CSF, dated 06/10/1998, for the basic formulation is for reference.

2. The CSF, dated 07/30/10, for the basic formulation is obsolete.

3. The CSF, dated 09/28/10, for the basic formulation is revised.

4. The registrant has indicated on the letter that the CSF, dated 07/30/10, for the basic formulation is to replace the CSF, dated 06/10/1998, for the basic formulation.

5. The CSF and the label have the same nominal.

CONCLUSIONS:

The CSF, dated 09/28/10, for the basic formulation is acceptable.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 30, 2010

MEMORANDUM

Subject: Efficacy Review for Virocid; EPA Reg. No. 71355-1; DP Barcode: D381154

From: Ibrahim Laniyan, Microbiologist
Product Science Branch
Antimicrobials Division (7510P)

Thru: Tajah Blackburn, Team Leader
Product Science Branch
Antimicrobials Division (7510P)

11/23/10

To: Cleiis Mixon / Velma Noble
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: CID Lines N.V.
Waterpoortstraat 2
B 8900 Ieper, Belgium- Europe

Formulation from the Label:

Active Ingredient	% by wt.
Alkyl Dimethyl Benzyl Ammonium Chloride (50% C14, 40% C12, 10% C16)	17.060 %
Didecyl Dimethyl Ammonium Chloride	7.800 %
Glutaraldehyde	10.725 %
Inert Ingredients	64.415 %
Total	100.000 %

I. BACKGROUND

The product, Virocid (EPA Reg. No. 71355-1), is an Agency approved disinfectant (bactericide, virucide, fungicide) for use on hard, non-porous surfaces in farm, animal, and poultry housing facilities and equipment, food processing plants and in veterinary hospitals. The applicant requested to amend the registration of this product to add claims for effectiveness against Human Influenza A virus (H1N1) and Swine Influenza virus (H1N1). The registrant also requested to add claims for previously rejected fourteen (14) microorganisms. The studies were conducted at ATS Labs, located at t285 Corporate Center Drive, Suite 100 in Eagan Minnesota.

This data package contained a letter from the applicant representative to EPA (dated June 30, 2010), three studies (MRID 481742-01 through 481742-03), Statements of No Data Confidentiality Claims for all three studies, and the proposed label.

II. USE DIRECTIONS

The product is designed to be used for disinfecting hard, non-porous surfaces on farm equipment, animal housing buildings, floors, walls, ceilings, counters, cages, feeding/drinking equipment, handling/restraining equipment, vehicles, hatchers, setters, trays, racks, carts, tables, chick boxes, and animal cages. The product may be used on hard, non-porous surfaces such as steel, copper, aluminum, finished wood, vinyl, plastics, glazed tiles, and sealed brick walls.

Directions on the proposed label provide the following information regarding preparation and use of the product as a disinfectant: Thoroughly clean surfaces with soap or detergent. Rinse with water. Saturate surfaces with the appropriate disinfection solution using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Rinse feeding and watering appliances with potable water before reuse.

The proposed label includes a table of the target organisms and the dilutions which are to be made to control each. Human Influenza A virus (H1N1) and Swine Influenza virus (H tN t) listed use dilution is1:400.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Virucides; The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered

acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

IV. COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 481742-01 "Efficacy Discussion" for Virocid, by Rhonda Jones. Study completion date – July 30, 2010.

This efficacy discussion gave reasons why studies were conducted on microorganisms using primary and secondary subculturing media as means of neutralization effectiveness instead of the presently used neutralization confirmation test.

2. MRID 481742-02 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces - Human Influenza A Virus (H1N1)," for Virocid, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – July 24, 2010; amended July 28, 2010. Project Number A07937.

This study was conducted against Human influenza A virus (H1N1), ATCC VR-1469, Strain A/PR/8/34, using Rhesus monkey kidney (RMK) cells (obtained fromViroMed Laboratories, Inc., Cell Culture Division) as the host system. Two lots (Lot Nos. S902501 and S902502) of the product, Virocid, were tested according to an ATS Lab protocol SRC46043009.FLUA (copy provided). Use solutions were prepared by adding 1.00 ml of the product to 399.0 ml of 400 ppm AOAC synthetic hard water (titrated at 396 ppm). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Minimum Essential Medium with 2% glycine was used as neutralizing medium. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C in a relative humidity of 40%. For each lot of product, separate dried virus film was exposed to 2.00 ml of use dilution for 10 minutes at ambient temperature. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were neutralized and diluted serially in Minimum Essential Medium with 1% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days to 10 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol amendment reported in the study was reviewed and found to be acceptable.

3. MRID 481616-02 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces - Swine Influenza A Virus (H1N1)," for Virocid, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – July 28, 2010. Project Number A07938.

This study was conducted against Swine Influenza A virus (H1N1), ATCC VR-333, Strain A/Swine/Iowa/15/30, using Rhesus monkey kidney (RMK) cells (obtained fromViroMed Laboratories, Inc., Cell Culture Division) as the host system. Two lots (Lot Nos. S90250 1 and S902502) of the product, Virocid, were tested according to an ATS Lab protocol SRC46042909.SFLU (copy provided). Use solutions were prepared by adding 1.00 ml of the product to 399.0 ml of 400 ppm AOAC synthetic hard water (titrated at 396 ppm). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Minimum Essential Medium with 2% glycine was used as neutralizing medium. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C in a relative humidity of 40%. For each lot of product, separate dried virus film was exposed to 2.00 ml of use dilution for 10 minutes at ambient temperature. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were neutralized and diluted serially in Minimum Essential Medium with 1% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days to 10 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

V. RESULTS

MRID Number	Organism	Results			Plate Recovery Control
			Lot No. S902501	Lot No. S902502	
481742-02	Human Influenza A virus (H1N1)	10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{5.5}$ $TCID_{50}$/0.1mL
		TCD_{50}/0.1mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
		$TCID_{50}$/0.1mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
		Log Reduction	≥4.0	≥4.0	
481742-03	Swine Influenza A virus (H1N1)	10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{6.0}$ $TCID_{50}$/0.1mL
		TCD_{50}/0.1mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
		$TCID_{50}$/0.1mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
		Log Reduction	≥4.5	≥4.5	

VI. CONCLUSIONS

1. The submitted efficacy discussion justified the use of primary and secondary subculture media as mean of neutralization in studies MRID Nos. 459190-01, 460499-01, and 460499-02.

2. The submitted efficacy data **support** the use of the product, Virocid, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a 10-minute contact time when diluted 1:400:

Human Influenza A virus (H1N1)	MRID 481742-02
Swine Influenza A virus (H1N1)	MRID 481742-03

Recoverable virus titers of at least 10^4 were achieved. Complete inactivation (no growth) was indicated in all dilutions tested. Human Influenza A virus (H1N1)

VII. LABEL

1. The proposed label claims that the product, Virocid, is an effective "one-step" disinfectant against the following microorganisms on hard, non-porous surfaces for a 10-minute contact time in the presence of 400 ppm hard water and a 5% organic soil load at the dilution listed:

Human Influenza A (H1N1) (ATCC VR-1469)	1:400 dilution
Swine Influenza A virus (H1N1) (ATCC VR-333)	1:400 dilution
Campylobacter jejuni (ATCC 33560)	1:400 dilution
Corynebacterium pseudotuberculosis (ATCC 19410)	1:400 dilution
Avibacterium (Haemophilus) paragallinarum (ATCC 29975)	1:400 dilution
Klebsiella pneumonia (ATCC 13883)	1:400 dilution
Listeria monocytogenes (ATCC 19115)	1:400 dilution
Mycoplasma gallisepticum (ATCC 19610)	1:400 dilution
Mycoplasma synoviae (ATCC 25204)	1:400 dilution
Ornithobacterium rhinotracheale (ATCC 51463)	1:400 dilution
Pasteurella multocida (ATCC 6529)	1:400 dilution
Salmonella enteritidis (ATCC 13076)	1:400 dilution
Fusarium dimerum (ATCC 16553)	1:400 dilution
Penicillium expansum (ATCC 7861)	1:400 dilution
Bordetella avium (ATCC 35086)	1:256 dilution
Salmonella enterica (pullorum) (ATCC 9120)	1:256 dilution

These claims are **acceptable** as they are supported by the submitted data.

2. The applicant must add **reference numbers** (like ATCC numbers) for all listed microorganisms.

SRC
Scientific & Regulatory
Consultants, Inc.

July 30, 2010

Velma Noble, PM 31
Document Processing Desk (AMEND)
Office of Pesticide Programs (7S04P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

SUBJECT: VIROCID
EPA Reg. No. 71355-1

Dear Velma,

On behalf of CID LINES NV/SA is an amendment with data for Virocid. This amendment is a PRIA action code A570 which is assigned a PRIA fee of $3308 and a 4 month review time. A copy of the confirmation of payment via www.pay.gov is attached.

The purpose of the submission is to:

- Add new claims for Human Influenza A virus (H1N1) and Swine Influenza A virus (H1N1). (See Volumes 3 – 4.)
- Add data previously rejected[1] to support
  - *Mycoplasma gallisepticum*[2],
  - *Mycoplasma synoviae,*
  - *Bordetella avium,*
  - *Klebsiella pneumoniae,*
  - *Ornithobacterium rhinotracheale,*
  - *Salmonella enterica (formerly S. enteritidis),*
  - *Salmonella enterica (formerly S. cholerasuis, serotype typhisuis)*
  - *Salmonella enterica (formerly S. pullorum),*
  - *Campylobacter jejuni,*
  - *Corynebacterium pseudotuberculosis,*
  - *Avibacterium paragellinarum (formerly H. paragallinarum),*
  - *Listeria monocytogenes,*
  - *Fusarium dimerum,* and
  - *Pencillium expansum*

[1] The studies for these organisms were assigned MRID 46049901 and 46049902. Rationale for accepting this data was provided to Tajah Black prior to filing this submission. Volume 2 of this submission provides justification for accepting this data.
[1] Strain designates (e.g. ATCC) are provided on enclosed data matrix.

- Upgraded the
  - first aid statements, to comply with PR Notice 2001-1,
  - precautionary statements to comply with the Labeling Review Manual Chapter 8, and
  - storage and disposal language to reflect the Container and Containment Review per PR Notice 2007-4.

Enclosed are 5 copies of labeling with the changes and deletions reflected. An electronic label named "071355-00001.2010728.Amend.pdf" is attached which incorporates all changes in proper electronic label format.

The CSF has been updated to reflect a change in ownership of the registered active ingredient, glutaraldehyde. [redacted] is now under the ownership of [redacted] requiring a change in the EPA registered active number from [redacted] to [redacted]. In addition, the [redacted] listed in Column 13 was corrected to reflect the total product weight as 100% by weight. This replaces the CSF dated 06/10/98.

Please contact me at (260) 244-6270 or shayes@srcconsultants.com if you have any questions regarding this submission.

Sincerely,

Sally Hayes
Agent, CID LINES NV/SA

cc: A. Francois, CID LINES

VIROCID

EPA Registration No: 71355-1

TRANSMITTAL DOCUMENT

1. Name and address of submitter:
   Scientific & Regulatory Consultants, Inc.
   PO Box 1014
   Columbia City, IN 46725

   AGENT FOR:
   CID LINES NV/SA
   Waterpoortstraat 2
   B 8900 IEPER BELGIUM

2. Regulatory action in support of which this package is submitted:
   AMENDMENT: PRIA Code A570, PRIA fee $3308

3. Transmittal date:
   July 30, 2010

4. Vol. 1 Administrative materials:
   A) Cover letter
   B) Copy of Agent Authorization
   C) Copy of PRIA II payment ($3308 for A570 Initial Registration)
   D) Application
   E) Certification with Respect to Citation of Data
   F) Data Matrix
   G) Formulator's Exemption Statement
   H) CSF dated 06/10/98
   I) 2 copies of revised CSF dated 07/28/10
   J) 1 copy of label with changes highlighted and deletions shown
   K) 5 copies of label without highlighting or deletions
   L) Electronic label 071355-00001.20100728.Amend.pdf

5. Vol. 2 Efficacy

48174201 A) Efficacy Discussion

6. Vol. 3 Efficacy

48174202 A) Guideline 91-2 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Human Influenza A (H1N1) (A07937)

7. Vol. 4 Efficacy

48174203 A) Guideline 91-2 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Swine Influenza A (H1N1) (A07938)

Company Official:	Sally Hayes
Company Name:	Agent for CID LINES NV/SA
Company Contact:	Sally Hayes Phone: 260-244-6270 E-mail: shayes@srcconsultants.com

VIROCID®

CONCENTRATED BROAD SPECTRUM DISINFECTANT

Active ingredients :

ALKYL* DIMETHYL BENZYL AMMONIUM CHLORIDE *(50% C14;40% C12;10% C16)	17.060 % (by wt)
DIDECYL DIMETHYL AMMONIUM CHLORIDE	7.800 %
GLUTARALDEHYDE	10.725 %
inert ingredients	64.415 %
	100.000 %

KEEP OUT OF REACH OF CHILDREN

DANGER

ViROCiD is effective against :

BACTERIA	Dilution
*Salmonella Choleraesuis (ATCC 10708)**	1:400
*Staphylococcus aureus (ATCC 6538)**	1:400
*Pseudomonas aeruginosa (ATCC 15442)**	1:400
[redacted]	1:400
	1:400
	1:400
	1:400
	1:400
	1:400
	1:400
	1:400
	1:400
	1:400
*Mycoplasma hyopneumoniae (ATCC 25934)**	1:400
*Streptococcus suis (ATCC 43765)**	1:400
*Salmonella choleraesuis subsp. Choleraesuis, serotype typhisuis (ATCC 8321)**	1:400
*Escherichia coli (ATCC 11229)**	1:400
	1:256
	1:256
FUNGUS *(on environmental surfaces)* :	
[redacted]	1:400
	1:400
Trichophyton mentagrophytes (ATCC 9533)	1:400
VIRUS *(on environmental surfaces)* :	
*Porcine circovirus, type II (PCV, PT-1 cell)**	1:200
*Pseudorabies (American BioResearch Laboratories)**	1:400
*Porcine Respiratory and Reproductive Syndrome (Arko Laboratories)**	1:400
*Avian Reovirus (Spafas Strain)**	1:256
*Marek's Disease (Spafas Strain)**	1:400
*Newcastle Disease (Spafas Strain)**	1:400
*Avian Influenza (Turkey/Wis/66 strain – H9N2)**	1:400
*Avian Infectious Laryngotracheitis (Charles River laboratories)**	1:400
*Infectious Bursal Disease of Chickens (SPAFAS Strain 2512)**	1:400
Algae and slime forming bacteria in recirculating water cooling systems and evaporative condensers	25-50 ppm

**in the presence of 400 ppm AOAC synthetic hard water and 5% soil load*

ACCEPTED
With COMMENTS
In EPA Letter Dated:
APR 7 2005

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide registered under EPA Reg. No. 71355-1

71355-1

D. Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and rinse with potable water before reuse.
E. Disinfection of equipment : Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure in the appropriate disinfection solution* for 10 minutes. Allow to air dry.
F. Fresh disinfection solution should be made daily.

2. Hatcheries :
Remove all animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, carts, sexing lables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with the appropriate disinfection solution* by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed or dried. Fresh disinfection solution should be made daily or if visibly soiled.

3. Food processing plants (including Chicken Processing Facilities) :
Before using this product, all food products and packaging materials must be removed from the room or carefully protected. Thoroughly clean all surfaces with soap or detergent, then rinse with water. Disinfect hard, non-porous surfaces by applying the appropriate disinfection solution* with a coarse spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

4. Trucks and other vehicles :
Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the appropriate disinfection solution* to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

5. Veterinary hospitals :
For disinfection of the following hard non-porous surfaces : floors, walls, ceilings, counters, cages, feeding/drinking equipment, and handling/restraining equipment. Remove animals and feed from the premises. Thoroughly clean all surfaces with soap or detergent, then rinse with water. Saturate surfaces with the appropriate disinfection solution* by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Immerse all leashes, muzzles, ropes or other types of equipment used to restrain or handle animals as well as shovels, scrapers, and forks used to remove manure and litter. Do not house livestock or employ equipment until surfaces have been absorbed or dried. Thoroughly scrub treated feeding and watering equipment with soap or detergent and rinse with potable water before reuse. Fresh disinfection solution should be made daily or if visibly soiled.

Preparation table :

dilution	*Preparation method*
1:1000	
1:400	⅛ fluid ounce per gallon of water
1:256	½ fluid ounce per gallon of water
1:200	⅝ fluid ounce per gallon of water

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<u>Sanitizing hatchery rooms, incubators and hatchers, poultry houses and livestock buildings by fogging</u>

A. Hatchery rooms :
Close room off so fog is confined to room to be treated. Prepare a stock solution of one (1) part VIROCID to four (4) parts water (25 fluid ounce VIROCID to 100 fluid ounce water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yard. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment
Note : The generated fog is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after the actual fogging. If the building or room must be entered, then the individuals

STORAGE AND DISPOSAL :

Do not contaminate water, food, or feed by storage and disposal
Storage : Store in a cool, dry place in tightly closed container away from children. Avoid temperatures below 23°F and above 113°F.
Disposal of pesticide : Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance.
Disposal of container : Triple rinse. Then offer for recycling or puncture and dispose in a sanitary landfill. Disposal by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

ENVIRONMENTAL HAZARDS :

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PRECAUTIONARY STATEMENTS

Hazard to humans and domestic animals
DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves. Harmful if inhaled. Avoid breathing vapor. Harmful if swallowed. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.
Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash before reuse.

LIMITED WARRANTY AND DISCLAIMER :

The manufacturer warrants (a) that this product conforms to the chemical description on the label ; (b) that this product is a reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions ; and (c) that the directions, warnings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warnings or cautions. Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, whether or not such liability is based in the contract, negligence, strict liability in tort or otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.

EPA Reg. N° : 71355-1 EPA Est. N° : 71355-BEL-001
BATCH N° : see top / bottom EXPIRY DATE : see top / bottom
Net contents : see top / bottom

Produced by :
CID LINES NV/SA - Waterpoortstraat 2 - B 8900 IEPER - BELGIUM - EUROPE
Phone: 011-32-57-217877 - Fax: 011-32-57-217879
http://www.cidlines.com - info@cidlines.com

CID LINES

APR 7 2005

71355-1

minutes. The dried virus films were completely covered with 2.0 mL of each use solution, and remained exposed to the product for 10 minutes at 20±2°C. After exposure, the plates were neutralized with 2.0 mL of fetal bovine serum containing 0.3% glycine. The plates were scraped with a cell scraper to re-suspend the contents, and the virus-disinfectant mixture was passed through a Sephacryl column, and diluted serially in Eagle's minimum essential media containing 10% fetal bovine serum (CCM). PT-1 cells in multi-well culture dishes were inoculated in quadruplicate with the dilutions. The cultures were incubated at 37±2°C in 5±1% CO_2 for 20-30 hours for viral adsorption. Post-adsorption, the media was aspirated and the host cells were washed and re-fed with CCM. The cells were incubated for 5-7 days. Post-incubation, the host cells were washed, fixed with tissue grade alcohol, and stained and read for infectivity. The plates were assayed by immunofluorescence assay. Controls included cell viability, virus stock titer, plate recovery, column titer, cytotoxicity, and neutralizer effectiveness. $FFFUD_{50}$/mL was calculated by the method of Reed and Muench.

Note: An initial test using D/E as the neutralizer did not produce the required 3 log reduction in virus titer. The study was repeated with the same product lots, using fetal bovine serum containing 0.3% glycine as the neutralizer.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

V RESULTS

MRID Number	Organism	No. Exhibiting Growth/Total No. Tested		Dried Carrier Count (CFU/ carrier)
		Lot No. 202890	Lot No. 202990	
460499-01	*Bordetella avium* (At a 1:400 dilution)	1° = 0/10 2° = 0/10	1° = 1/10 2° = 0/10	5.8×10^5
	(At a 1:256 dilution)	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	1.9×10^6
460499-01	*Campylobacter jejuni*	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	3.4×10^5
460499-01	*Corynebacterium pseudotuberculosis*	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	1.1×10^5
460499-01	*Haemophilus paragallinarum*	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	8.6×10^5
460499-01	*Klebsiella pneumoniae*	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	2.9×10^6

tested. Each carrier was immersed in a suspension of the test organism, dried for 40 minutes at 37±1°C, and then exposed to the use solution for 10 minutes at 20±1°C. Following exposure, each carrier was transferred to an individual tube containing neutralizer. After 30 minutes, the carriers were transferred from primary subculture tubes into secondary subculture tubes containing neutralizer. All subcultures were incubated for 48±2 hours at 37±1°C, and then observed for the presence or absence of visible growth.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable with the exception of the plate count of *P. multocida* being 7.3×10^3.

2. MRID 460499-02 " AOAC Use-Dilution Method Fungicidal Modification for Virocid," by Kathleen A. Baxter. Study conducted by Hill Top Research, Inc. Study completion date – December 12, 2002. HTR Study No. 02-120836-106.

This study was conducted against *Aspergillus fumigatis* (ATCC 10894), *Penicillium expansum* (ATCC 7861), and *Fusarium dimerum* (ATCC 16553). Two lots (Lot Nos. 202890 and 202990) of the product, Virocid, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990 and the AOAC Fungicidal Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. A use solution was prepared by diluting 1.25 mL of the product in 500 mL of 400 ppm AOAC synthetic hard water (titration results not provided; a 1:400 dilution). Horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) polished stainless steel cylinder carriers per product lot were immersed in a suspension of the test organism for 15 minutes. The carriers were dried for 40 minutes at 37±1°C, and then exposed to the use solution for 10 minutes at 20±1°C. The carriers containing *Aspergillus fumigatis* or *Fusarium dimerum* were transferred to Potato Dextrose Broth with AOAC Stock Neutralizer to neutralize. The carriers containing *Penicillium expansum* were transferred to Malt Extract Broth with AOAC Stock Neutralizer to neutralize. After 30 minutes, the carriers were transferred from primary subculture tubes into secondary subculture tubes containing neutralizer. All subcultures were incubated for 7-8 days at 25±1°C, and then observed for the presence or absence of visible growth. Controls included dried carrier counts, neutralizer effectiveness, and viability.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

3. MRID 459190-01 "Virucidal Effectiveness Test, Porcine circovirus" for Virocid by David Kang. Study conducted at MicroBioTest Inc. Study completion date – December 24, 2002. Laboratory Project Identification Number 431-104.

This study was conducted against Porcine circovirus, type II (obtained from American BioResearch Lab, Sevierville, TN), using PT-1 cells (obtained from American BioResearch Lab, Sevierville, TN) as the host system. Two lots (Lot Nos. 203890 and 204090) of the product, Virocid, were tested according to a MicroBioTest Protocol "Virucidal Effectiveness Test, Porcine circovirus," dated September 26, 2002 (copy provided). ASTM Method E 1053-97 was referenced. Three different use solutions of the product were prepared (i.e., 1:67, 1:100, and 1:200) using sterile deionized water. The stock virus titer contained a 5% organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried at room temperature for 30-60

MRID Number	Organism	No. Exhibiting Growth/Total No. Tested		Dried Carrier Count (CFU/ carrier)
		Lot No. 202890	Lot No. 202990	
460499-01	*Salmonella choleraesuis pullorum* (At a 1:400 dilution)	1° = 1/10 2° = 0/10	1° = 0/10 2° = 0/10	1.3×10^5
	(At a 1:256 dilution)	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	1.6×10^6

MRID Number	Organism	No. Exhibiting Growth/Total No. Tested		Dried Carrier Count (conidia/carrier)
		Lot No. 202890	Lot No. 202990	
460499-02	*Aspergillus fumigatus*	1° = 5/10 2° = 8/10	1° = 7/10 2° = 7/10	1.9×10^5
	Fusarium dimerum	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	2.2×10^5
	Penicillium expansum	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	1.1×10^4

MRID Number	Organism	Results			Plate Recovery Control ($FFFUD_{50}$/ mL)
			Lot No. 203890	Lot No. 204090	
459190-01	*Porcine circovirus* (At a 1:200 dilution)	10^{-2} dilution	Cytotoxicity	Cytotoxicity	$\geq 10^{6.23}$
		10^{-3} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	
		$FFFUD_{50}$/mL	$\leq 10^{2.5}$	$\leq 10^{2.5}$	
		Log reduction	$\geq 3.73 \log_{10}$	$\geq 3.73 \log_{10}$	

MRID Number	Organism	No. Exhibiting Growth/Total No. Tested		Dried Carrier Count (CFU/ carrier)
		Lot No. 202890	Lot No. 202990	
460499-01	*Listeria monocytogenes*	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	2.9×10^6
460499-01	*Mycoplasma gallisepticum*	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	2.6×10^5
460499-01	*Mycoplasma synoviae*	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	1.0×10^5
460499-01	*Ornithobacterium rhinotracheale*	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	1.3×10^7
460499-01	*Pasteurella multocida*	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	7.3×10^3
460499-01	*Salmonella choleraesuis enteritidis*	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	5.5×10^6

3. The submitted efficacy data (MRID No. 460499-02) do not support the use of the product, Virocid, as a disinfectant with fungicidal activity against on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1:400 dilution. Growth was observed in the subcultures. In addition, the dried carrier counts did not meet the 10^6 minimum for testing as specified in EPA DIS/TSS-6.

4. The submitted efficacy data (MRID No. 459190-01) does not support the use of the product, Virocid, as a disinfectant with virucidal activity against *Porcine circovirus*, type II on hard, non-porous surfaces for a contact time of 10 minutes in the presence of a 5% organic soil load at the label-specified dilution of 1:200. Cytotoxicity was observed at 10^{-2}. Complete inactivation (no growth) was indicated in all higher dilutions tested. A log reduction of at least 3.0 was calculated. A recoverable virus titer of at least 10^4 was reported. However, the virucidal study was not conducted in the presence of 400 ppm AOAC hard water, as prescribed on the label. In addition, the report does not state how the dilutions of 1:67, 1:100, and 1:200 were made.

VII RECOMMENDATIONS

1. The proposed label claims (as supported by MRID No. 460499-01) are not currently acceptable regarding the use of the product, Virocid, as a disinfectant on hard, non-porous surfaces against the following organisms for a contact time of 10 minutes in the presence of 400 ppm hard water and a 5% organic soil load at the dilution listed:

Bordetella avium	1:256 dilution
Campylobacter jejuni	1:400 dilution
Corynebacterium pseudotuberculosis	1:400 dilution
Haemophilus paragallinarum	1:400 dilution
Klebsiella pneumoniae	1:400 dilution
Listeria monocytogenes	1:400 dilution
Mycoplasma gallisepticum	1:400 dilution
Mycoplasma synoviae	1:400 dilution
Ornithobacterium rhinotracheale	1:400 dilution
Pasteurella multocida	1:400 dilution
Salmonella choleraesuis serotype enteritidis	1:400 dilution
Salmonella choleraesuis serotype *pullorum*	1:256 dilution

The registrant must either submit HTR Study No. 02-120055-106 to the EPA so that neutralizer effectiveness can be confirmed or delete the all references to the above mentioned organisms from the label. In addition, the applicant must conduct the study again to obtain a dried carrier count of 1.0×10^4 for *Pasteurella multocida*.

2. The proposed label claims (as supported by MRID No. 460499-02) are not acceptable regarding the use of the product, Virocid, as a fungistat against *Fusarium dimerum*, *Aspergillus fumigatus*, and *Penicillium expansum* on hard, non-porous surfaces for a contact time of 10 minutes. The registrant must either conduct the tests again against *Fusarium dimerum*, *Aspergillus fumigatus*, and *Penicillium expansum* until the data fully meets DIS/TSS-6 requirements or delete all references must delete all references to *Fusarium dimerum*, *Aspergillus fumigatus*, and *Penicillium expansum* from the label. The registrant must also

VI CONCLUSIONS

1. The submitted efficacy data (MRID No. 460499-01) does not currently support the use of the product, Virocid, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at the dilutions listed:

Bordetella avium	1:256 dilution
Campylobacter jejuni	1:400 dilution
Corynebacterium pseudotuberculosis	1:400 dilution
Haemophilus paragallinarum	1:400 dilution
Klebsiella pneumoniae	1:400 dilution
Listeria monocytogenes	1:400 dilution
Mycoplasma gallisepticum	1:400 dilution
Mycoplasma synoviae	1:400 dilution
Ornithobacterium rhinotracheale	1:400 dilution
Pasteurella multocida	1:400 dilution
Salmonella choleraesuis serotype enteritidis	1:400 dilution
Salmonella choleraesuis serotype *pullorum*	1:256 dilution

The registrant failed to provide sufficient detail about neutralizer effectiveness testing. Neutralizer effectiveness was studied and reported in HTR Study No. 02-120055-106, which was not included in the data package. The registrant needs to submit this study to the Agency so that the Agency can confirm that neutralizer effectiveness studies were conducted against all of the tested organisms.

When the product was initially tested using a 1:400 dilution on the organisms of *B. avium* and *Salmonella choleraesuis* serotype *pullorum*, one carrier was positive for growth.

The dried carrier count for *Pasteurella multocida* was 7.3×10^3 instead of the required 1.0×10^4.

2. The submitted efficacy data (MRID No. 460499-02) does not support the use of the product, Virocid, as a disinfectant with fungicidal activity against *Fusarium dimerum, Aspergillus fumigatus*, and *Penicillium expansum* on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1:400 dilution. The registrant failed to provide sufficient detail about neutralizer effectiveness testing. Neutralizer effectiveness was studied and reported in HTR Study No. 02-120055-106, which was not included in the data package. The registrant needs to submit this study to the Agency so that the Agency can confirm that neutralizer effectiveness studies were conducted against the tested organisms.

Further, the dried carrier count for all the organisms does not meet the required conidia per carrier count of 1.0×10^6 per DSS/TSS-6.

When the product was tested against *Aspergillus fumigatis*, the numbers in the summary table on page 7 of 32 seem to contradict the table on page 8 of 32. Page 7 seems to state that nine carriers of each batch showed positive growth, whereas, page 8 seems to indicate that growth was shown on 5/10 and 7/10 in the first subculture and 8/10 and 7/10 in the second subculture.

7. The potential label asserts that the product may be used for the disinfection of floors. Presently, the Agency does not allow the disinfection of floors. The registrant must remove any reference to the disinfection of floors from the label.

8. On the proposed label under the precautionary statements, the statement "Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse" must be revised to read "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse."

9. The first sentence under the "**If Swallowed**" first aid statement must read "Call a poison control center or doctor *immediately* for treatment advice."

10. The registrant should make the following revisions to the submitted label:

a. correct the spelling of "*Orinthobacterium*" so it reads "*Ornithobacterium*"
b. correct the spelling of "course spray" so it reads "coarse spray"

submit HTR Study No. 02-120055-106 to the Agency so that neutralizer effectiveness can be confirmed. The registrant also needs the clarify the confusion on the test against *Aspergillus fumigatis*. In MRID 460499-02, nine carriers of each batch showed positive growth, whereas, page 8 seems to indicate that growth was shown on 5/10 and 7/10 in the first subculture and 8/10 and 7/10 in the second subculture.

3. The proposed label claims (as supported by MRID No. 459190-01) are not acceptable regarding the use of the product, Virocid, as a virucide against *Porcine circovirus*, type II on hard, non-porous surfaces. The registrant either needs to reconduct the study in 400 ppm AOAC hard water and state how the 1:67, 1:100, and 1:200 dilutions were made or delete all references to *Porcine circovirus*, type II from the label.

VIII LABELING COMMENTS

1. This product is registered as an animal premises disinfectant. The proposed label that is pinpunched 04/09/03 requests the use of human health pathogens which are not supported by any use sites. The Agency requires that the registrant provide use sites and directions for use which are associated with the proposed health claims.

2. The prospective label lists the use dilutions for disinfection of various sites; however, it does not have use directions for how to make the use dilutions. The label must have use directions on how to dilute the formulation. For example, the label must state, "To get a 1:400 dilution of Virocid, the you must mix 5 tablespoons of Virocid in 200 gallons of water."

3. The submitted label states that the product may be used on "finished wood." This is an unacceptable use because wood is naturally porous. If the registrant intends to use the product on "finished wood," the label must specify that the wood is "sealed and finished;" otherwise, this use must be removed from the label.

4. The draft label claims that the product can be used on "plastics." This use is unacceptable because some plastics are porous. On the label, the registrant must specify on which types of plastics that the product is to be used.

5. The proposed label contends that the product may be used on brick walls, which are porous surfaces. If the registrant intends to use the product on brick walls, the label must specify that the brick walls are "sealed," otherwise, this use must be removed from the label.

6. The registrant wishes to use the product on sandwich panels. The "sandwich panels" on the proposed label must be replaced by "aluminum sandwich panels." If the registrant wishes to use the product on other sandwich panels, the label must specify the material of which the sandwich panel is made.

FEB 2 - 2004

Ms. Olivia Laird
Agent for Virocid
Laird's Regulatory Consultant, Inc.
501 S. Lincoln Ave
Sterling, VA 20164-2024

Subject: Virocid
EPA Registration No. 71355-1
Amendment Date: April 7, 2003
EPA Receipt Date: August 8, 2003

Dear Ms. Olivia Laird,

The following amendment submitted in connection with registration under FIFRA 3(c)(7)(A) is unacceptable for the following reasons.

- Addition of microorganisms

Data Deficiencies

Data Requirement	Means of Support	Status
AOAC Use-Dilution Method for Virocid Batch 202890 & 202990	Submitted study, MRID 460499-01	Unacceptable
AOAC Use-Dilution Method, Fungicidal Modification	Submitted study, MRID 460499-02	Unacceptable
Virucidal Effectiveness Test - Porcine Circovirus	Submitted study, MRID 459190-01	Unacceptable

The efficacy data in MRID No. 460499-01 is unacceptable to support the use of this product as a disinfectant against *Bordetella avium, Campylobacter jejuni, Corynebacterium pseudotuberculosis, Haemophilus paragallinarum, Listeria monocytogenes, Klebsiella pneumoniae, Mycoplasma gallisepticum, Mycoplasma synoviae, Ornithobacterium rhinotracheale, Pasteurella multocida, Salmonella choleraesuis* serotype *enteritidis,* and *Salmonella choleraesuis* serotype *pullorum* because insufficient information was provided about the neutralizer effectiveness testing. Also, the dried carrier count for *Pasteurella multocida* was 7.3×10^3 instead of the required 1.0×10^4.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

January 2, 2004

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 71355-1
DP Barcode: D294304

From: Chris Jiang, Chemist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Emily Mitchell, Team Leader EM 1/9/04
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

To: Velma Noble, PM 31 / Jackie Campbell-McFarlane
Regulatory Management Branch I
Antimicrobials Division (7510C)

Applicant: CID LINES N.V.
8900 Ieper, Belgium

Formulation From Label:

Active Ingredient(s)	% by wt
Alkyl * dimethyl benzyl ammonium chloride	
* C_{14}, 50 %; C_{12}, 40 %; C_{16}, 10 %	17.060 %
Didecyl dimethyl ammonium chloride	7.800 %
Glutaraldehyde	10.725 %
Inert Ingredient(s)	64.415 %
Total	100.000 %

I BACKGROUND

The product, Virocid (EPA Reg. No. 71355-1), is an EPA-approved disinfectant (bactericide, fungicide, virucide) for use on hard, non-porous surfaces in animal housing facilities and in veterinary hospitals. The label claims that the product is effective "in the presence of 400 ppm AOAC synthetic hard water and 5% soil load." The applicant requested an amendment to the registration of this product to add claims for effectiveness against additional microorganisms, specifically *Bordetella avium* (ATCC 35086), *Campylobacter jejuni* (ATCC 33560), *Corynebacterium pseudotuberculosis* (ATCC 19410), *Klebsiella pneumoniae* (ATCC 13883), *Listeria monocytogenes* (ATCC 19115), *Ornithobacterium rhinotracheale* (ATCC 51463), *Pasteurella multocida* (ATCC 6529), *Salmonella choleraesuis enteritidis* (ATCC 13076), *Haemophilus paragallinarum* (ATCC 29975), *Mycoplasma gallisepticum* (ATCC 19610), *Mycoplasma synoviae* (ATCC 25204), *Salmonella choleraesuis pullorum* (ATCC 9120), *Penicillium expansum* (ATCC 7861), *Fusarium dimerum* (ATCC 16553), and *Porcine circovirus*, type II. Studies were conducted at Hill Top Research, Inc., located at Main and Mill Streets in Miamiville, OH 45147; and MicroBioTest, Inc., located at 105B Carpenter Drive in Sterling, VA 20164.

This data package contained EPA Form 8570-1 (Application for Pesticide), three studies (MRID Nos. 460499-01, 460499-02, and 459190-01), Statements of No Data Confidentiality Claims for all three studies, the proposed label, and the last accepted label (dated June 26, 2003).

II USE DIRECTIONS

The product is designed to be used for disinfecting hard, non-porous surfaces such as sandwich panels, feeding/drinking equipment, hatchers, setters, trays, racks, carts, tables, cages, floors, walls, ceilings, counters, and handling/restraining equipment. The label indicates that the product may be used on hard, non-porous surfaces such as stainless, galvanized, and painted steel, copper, aluminum, finished wood, vinyl, plastics, glazed tiles, and brick walls. Directions on the proposed label provided the following information regarding preparation and use of the product as a disinfectant: Remove animals and feed from the premises. Remove all litter and manure. Clean all surfaces with soap or detergent and rinse with water. Saturate the surface with the appropriate disinfectant solution (1:400 in most cases) using a coarse spray, mop, or sponge. Leave on surface for 10 minutes. Allow to air dry before allowing animals or feed into the area. Scrub feeding and watering equipment with soap and detergent. A potable water rinse is required for all surfaces that come into contact with food.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces -- Additional Microorganisms

Effectiveness of disinfectants against specific microorganisms other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, but not including viruses, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different batches. To support

products labeled as "disinfectants" for specific microorganisms (other than those microorganisms named in the above test methods), killing of the specific microorganism on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10^4 microorganisms survived the carrier-drying step. These Agency standards are presented in DIS/TSS-01.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi)

The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data derived from each of 2 product samples representing 2 different batches using the AOAC Fungicidal Test. The highest dilution that kills all fungal spores is the minimum effective concentration. These Agency standards are presented in DIS/TSS-6.

Alternatively, the AOAC Use-Dilution Method may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. If the product is intended to be used as a spray product, the AOAC Germicidal Spray Products as Disinfectants Method must be employed. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples representing 2 different batches must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required. These Agency standards are also presented in DIS/TSS-6.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used in developing data for virucides intended for use upon dry inanimate, environmental surfaces (e.g., floors, tables, cleaned dried medical instruments). To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different batches of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

Supplemental Claims

An antimicrobial agent identified as a "one-step" cleaner-disinfectant, cleaner-sanitizer, or one intended to be effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. These Agency standards are presented in DIS/TSS-2. The hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish disinfectant efficacy

in hard water, all microorganisms (i.e., bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level. These Agency standards are also presented in DIS/TSS-2.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 460499-01 "AOAC Use-Dilution Method for Virocid," by Kathleen A. Baxter. Study conducted by Hill Top Research, Inc. Study completion date – March 4, 2003. HTR Study No. 02-120830-106.

This study was conducted against *Bordetella avium* (ATCC 35086), *Campylobacter jejuni* (ATCC 33560), *Corynebacterium pseudotuberculosis* (ATCC 19410), *Haemophilus paragallinarum* (ATCC 29975), *Klebsiella pneumoniae* (ATCC 13883), *Listeria monocytogenes* (ATCC 19115), *Mycoplasma gallisepticum* (ATCC 19610), *Mycoplasma synoviae* (ATCC 25204), *Ornithobacterium rhinotracheale* (ATCC 51463), *Pasteurella multocida* (ATCC 6529), *Salmonella choleraesuis* serotype *enteritidis* (ATCC 13076), and *Salmonella choleraesuis* serotype *pullorum* (ATCC 9120) in the presence of a 5% organic soil load (horse serum). Two lots (Lot Nos. 202890 and 202990) of the product, Virocid, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. A use solution of the product was prepared by diluting 2.5 mL of the product with 1000 mL of 400-405 ppm AOAC synthetic hard water (a 1:400 dilution) or by diluting 1.25 mL of the product with 500 mL of 400-405 ppm AOAC synthetic hard water (a 1:400 dilution). Ten (10) stainless steel cylinder carriers per product lot per organism were tested. Each carrier was immersed in a suspension of the test organism. The carriers were dried for 40 minutes at 37±1°C (at 35±1°C for *Ornithobacterium rhinotracheale*), and then exposed to the use solution for 10 minutes at 20±1°C. Following exposure, each carrier was transferred to an individual tube containing neutralizer (i.e., Letheen Broth for studies against *Bordetella avium, Klebsiella pneumoniae, Ornithobacterium rhinotracheale, Salmonella choleraesuis* serotype *enteritidis*, and *Salmonella choleraesuis* serotype *pullorum*; Brain Heart Infusion Broth with AOAC Stock Neutralizer (BHIB+) for studies against *Campylobacter jejuni, Corynebacterium pseudotuberculosis, Listeria monocytogenes*, and *Pasteurella multocida*; BHIB+ with chicken serum for studies against *Haemophilus paragallinarum*; Mycoplasma Medium for studies against *Mycoplasma gallisepticum*; and Modified Chalquist Antigen Medium for studies against *Mycoplasma synoviae*). After 30 minutes, the carriers were transferred from primary subculture tubes into secondary subculture tubes containing the same neutralizer used previously. All subcultures were incubated for 48±2 hours at 37±1°C with the following exceptions: for studies against *Ornithobacterium rhinotracheale*, subcultures were incubated at 35±2°C; for studies against *Campylobacter jejuni* and *Haemophilus paragallinarum*, subcultures were incubated in 5% CO_2; for studies against *Mycoplasma gallisepticum*, subcultures were incubated for 5 days at 37±1°C in 5% CO_2; for studies against *Mycoplasma synoviae*, subcultures were incubated for 71.5 hours at 37±1°C in 5% CO_2. After incubation, all subcultures were observed for the presence or absence of visible growth. Controls included dried carrier counts, neutralizer effectiveness, and viability.

Testing was repeated against *Bordetella avium* (ATCC 35086) and *Salmonella choleraesuis* serotype *pullorum* (ATCC 9120) using a 1:256 use solution. In these two studies, a use solution was prepared by diluting 1.95 mL of the product in 500 mL of 400 ppm AOAC synthetic hard water (titrated at 405 ppm). Ten (10) carriers per product lot per organism were

DATA PACKAGE BEAN SHEET

Date: 16-Aug-2010

Decision #: 438047
DP #: (381153)
PRIA
Parent DP #:
Submission #: 879635

* * * Registration Information * * *

Registration: 71355-1 - VIROCID
Company: 71355 - CID LINES N.V.
Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855
Risk Manager Reviewer: Cletis Mixon CMIXON
Sent Date: _____ Calculated Due Date: 23-Dec-2010 Edited Due Date: _____
Type of Registration: Product Registration - Section 3
Action Desc: (A570) AMENDMENT;NON-FAST TRACK;
Ingredients: See page 2

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 16-Aug-2010 Due Back: _____
DP Ingredient: See page 2

OP Title: _____
CSF Included: ◯ Yes ● No Label Included: ◯ Yes ● No Parent DP #: _____

120/90

Assigned To		Date In	Date Out	
Organization:	AD / PSB	8/16/10		Last Possible Science Due Date: 23-Nov-2010
Team Name:	CTT	8/16/10	9/30/10	Science Due Date: 10/29/10
Reviewer Name:	Karen	8/17/10	9/27/10	Sub Data Package Due Date: 11/12/10
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Karen - Registrant has submitted CSF to be reviewed.

RECEIVED 8/16/10

Cid Lines, 71355-1
Jacqueline Campbell-McFarlane to: Cletis Mixon 12/15/2010 11:44 AM
Cc: Velma Noble

Hi, Jamil

The precautionary statements look ok. The only concern that I have is regarding the fogging section. I would add the following statements to appear before the directions for fogging (i.e. as the first statements in the section.)

All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices.

If you have any questions, let me know.

Jacqueline McFarlane
EPA (7510P)
Antimicrobials Division
1200 Pennsylvania Ave, NW
Washington, DC 20460
(703) 308-6416
(703) 308-6467 (fax)

Virocid, EPA REG. No. 71355-1
shayes
to:
Juan Negron
09/28/2010 11:06 AM
Please respond to shayes
Show Details

Juan,

Attached is the CSF for EPA Reg. No. 71355-1. The quat CAS No. has been changed to 68424-85-1 per your request.

Thanks for your help with this submission.

Sally Hayes
Scientific & Regulatory Consultants, Inc.
260-244-6270
www.srcconsultants.com

SRC
Scientific & Regulatory
Consultants, Inc.

July 30, 2010

Velma Noble, PM 31
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

SUBJECT: VIROCID
EPA Reg. No. 71355-1

Dear Velma,

On behalf of CID LINES NV/SA is an amendment with data for Virocid. This amendment is a PRIA action code AS70 which is assigned a PRIA fee of $3308 and a 4 month review time. A copy of the confirmation of payment via www.pay.gov is attached.

The purpose of the submission is to:

- Add new claims for Human Influenza A virus (H1N1) and Swine Influenza A virus (H1N1). (See Volumes 3 – 4.)
- Add data previously rejected[1] to support
  - *Mycoplosma gallisepticum*[2],
  - *Mycoplasmo synoviae,*
  - *Bordetello ovium,*
  - *Klebsiella pneumonioe,*
  - *Ornithobocterium rhinotracheale,*
  - *Salmonella enterico (formerly S. enteritidis),*
  - *Salmonella enterica (formerly S. cholerasuis, serotype typhisuis)*
  - *Solmonella enterico (formerly S. pullorum),*
  - *Compylobacter jejuni,*
  - *Corynebocterium pseudotuberculosis,*
  - *Avibocterium paragellinarum (formerly H. parogallinarum),*
  - *Listerio monocytogenes,*
  - *Fusarium dimerum,* and
  - *Pencillium exponsum*

[1] The studies for these organisms were assigned MRID 46049901 and 46049902. Rationale for accepting this data was provided to Tajah Black prior to filing this submission. Volume 2 of this submission provides justification for accepting this data.

[2] Strain designates (e.g. ATCC) are provided on enclosed data matrix.

Inert ingredient information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

- Upgraded the
  - first aid statements, to comply with PR Notice 2001-1,
  - precautionary statements to comply with the Labeling Review Manual Chapter 8, and
  - storage and disposal language to reflect the Container and Containment Review per PR Notice 2007-4.

Enclosed are 5 copies of labeling with the changes and deletions reflected. An electronic label named "071355-00001.2010728.Amend.pdf" is attached which incorporates all changes in proper electronic label format.

The CSF has been updated to reflect a change in ownership of the registered active ingredient, glutaraldehyde. [redacted] is now under the ownership of [redacted] requiring a change in the EPA registered active number from [redacted] to [redacted] In addition, the [redacted] listed in Column 13 was corrected to reflect the total product weight as 100% by weight. This replaces the CSF dated 06/10/98.

Please contact me at (260) 244-6270 or shayes@srcconsultants.com if you have any questions regarding this submission.

Sincerely,

Sally Hayes
Agent, CID LINES NV/SA

cc: A. Francois, CID LINES

VIROCID

EPA Registration No: 71355-1

TRANSMITTAL DOCUMENT

1. Name and address of submitter:
   Scientific & Regulatory Consultants, Inc.
   PO Box 1014
   Columbia City, IN 46725

   AGENT FOR:
   CID LINES NV/SA
   Waterpoortstraat 2
   B 8900 IEPER BELGIUM

2. Regulatory action in support of which this package is submitted:
   AMENDMENT: PRIA Code AS70, PRIA fee $3308

3. Transmittal date:
   July 30, 2010

4. Vol. 1 Administrative materials:
   A) Cover letter
   B) Copy of Agent Authorization
   C) Copy of PRIA II payment ($3308 for A570 Initial Registration)
   D) Application
   E) Certification with Respect to Citation of Data
   F) Data Matrix
   G) Formulator's Exemption Statement
   H) CSF dated 06/10/98
   I) 2 copies of revised CSF dated 07/28/10
   J) 1 copy of label with changes highlighted and deletions shown
   K) S copies of label without highlighting or deletions
   L) Electronic label 07135S-00001.20100728.Amend.pdf

5. Vol. 2 Efficacy

48174201 A) Efficacy Discussion

6. Vol. 3 Efficacy

48174202 A) Guideline 91-2 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Human Influenza A (H1N1) (A07937)

7. Vol. 4 Efficacy

48174203 A) Guideline 91-2 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Swine Influenza A (H1N1) (A07938)

Company Official:	Sally Hayes
Company Name:	Agent for CID LINES NV/SA
Company Contact:	Sally Hayes Phone: 260-244-6270 E-mail: shayes@srcconsultants.com

OK As Per Dennis

VIROCID

CONCENTRATED BROAD SPECTRUM DISINFECTANT

12/15/10

Active Ingredients:	
ALKYL *DIMETHYL BENZYL AMMONIUM CHLORIDE *(50% C_{14}; 40% C_{12}; 10% C_{16})	17.060%
DIDECYL DIMETHYL AMMONIUM CHLORIDE	7.800%
GLUTARALDEHYDE	10.725%
Other Ingredients:	64.415%
Total	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

VIROCID is effective against:

BACTERIA	DILUTION
Salmonella ~~Choleraesuis (ATCC 10708)~~ enterica (formerly *S. choleraesuis*)*	1:400
*Staphylococcus aureus ~~(ATCC 6538)~~**	1:400
Pseudomonas aeruginosa (~~ATCC 15442~~)*	1:400
*Campylobacter jejuni**	1:400
*Corynebacterium pseudoluberculosis**	1:400
Avibacterium paragallinarum (formerly *H. paragallinarum*)*	1:400
*Klebsiella pneumoniae**	1:400
*Listeria monocytogenes**	1:400
*Mycoplasma gallisepticum**	1:400
*Mycoplasma synoviae**	1:400
*Ornithobacterium rhinotracheale**	1:400
Salmonella enterica (formerly *S. enteritidis*)*	1:400
*Mycoplasma hyopneumoniae***	1:400
*Streptococcus suis**	1:400
Salmonella enterica ~~cholerasuis, serotype typhisuis (ATCC 8321)~~ (formerly *S. typhisuis*)*	1:400
*Escherichia coli**	1:400
*Bordetella avium**	1:256
Salmonella enterica (formerly *S. pullorum*)*	1:256
FUNGUS (on environmental surfaces)	
*Fusarium dimerum**	1:400
*Penicillium expansum**	1:400
Trichophyton mentagrophytes	1:400
VIRUS (on environmental surfaces)	
Porcine circovirus, type II [PCV, PT-1 cell]*	1:200
Pseudorabies [American BioResearch Laboratories]*	1:400
Porcine Respiratory and Reproductive Syndrome [Arko Laboratories]*	1:400
Avian Reovirus [Spafas Strain]*	1:256
Marek's Disease [Spafas Strain]*	1:400
Newcastle Disease [Spafas Strain]*	1:400
Avian Influenza [Turkey/Wis/66 strain-H9N2]*	1:400
Human Influenza A (H1N1)*	1:400
Swine Influenza A (H1N1)*	1:400
Avian Infectious Laryngotracheitis [Charles River Laboratories]*	1:400
Infectious Bursal Disease [Spafas Strain 2512]*	1:400
Algae and slime forming bacteria in recirculating water cooling systems and evaporative condensers	**25-50 ppm**
*in the presence of 400 ppm AOAC synthetic hard water and 5% soil load **in the presence of 400 ppm AOAC synthetic hard water and 25% soil load	

Note: Bracketed[ ]information is optional text. Text separated by a comma(,)denotes–and/or-options. {Bracketed Text}is for administrative purposes only and will not appear on the printed label.

FIRST AID ~~STATEMENTS~~	
IF IN EYES	• Hold eye~~lids~~ open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing ~~eyes~~. • Call a poison control center or doctor for treatment advice.
IF ON SKIN ~~OR CLOTHING~~	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything ~~by mouth~~ to an unconscious person.
IF INHALED	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
[For emergency information on [product, use, etc.], call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222.] **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Have a product container or label with you when calling the poison control center, doctor, or going for medical treatment.	

APPLICATION:

Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment:

1. Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings)
2. Hatchers, setters, and chick processing facilities
3. Food processing plants (slaughterhouses)
4. Trucks and other vehicles
5. Veterinary hospitals

Sanitizing hatchery rooms, incubators, and hatchers, poultry houses and livestock buildings by fogging.
Control of algae and slime forming bacteria in recirculating water cooling systems and evaporative condensers.

DIRECTIONS FOR USE:

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment:

1. **Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings):**
   For disinfection of hard, non-porous surfaces: stainless, galvanized and painted steel, copper, aluminum, finished wood, vinyl, plastics, glazed tiles, sealed brick walls, aluminum sandwich panels and feeding/drinking equipment:
   A. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
   B. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with the appropriate disinfection solution† by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
   C. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried.
   D. Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and rinse with portable water before reuse.

E. Disinfection of equipment: Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure in the appropriate disinfection solution† for 10 minutes. Allow to air dry.
F. Fresh disinfection solution should be made daily or if visibly soiled.

2. **Hatcheries:**
Remove all animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, carts, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with the appropriate disinfection solution† by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed or dried. Fresh disinfection solution ~~should~~ must be made daily or if visibly soiled.

3. **Food processing plants (including Chicken Processing Facilities):**
Before using this product, all food products and packaging materials must be removed from the room or carefully protected. Thoroughly clean all surfaces with soap or detergent, then rinse with water. Disinfect hard, non-porous surfaces by applying the appropriate disinfection solution† with a coarse spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

4. **Trucks and other vehicles:**
Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the appropriate disinfection solution† to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

5. **Veterinary hospitals:**
For disinfection of the following hard non-porous surfaces: floors, walls, ceilings, counters, cages, feeding/drinking equipment, and handling/restraining equipment. Remove animals and feed from the premises. Thoroughly clean all surfaces with soap or detergent, then rinse with water. Saturate surfaces with the appropriate disinfection solution† by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Immerse all leashes, muzzles, ropes or other types of equipment used to restrain or handle animals as well as shovels, scrapers, and forks used to remove manure and litter. Do not house livestock or employ equipment until surfaces have been absorbed or dried. Thoroughly scrub treated feeding and watering equipment with soap or detergent and rinse with potable water before reuse. Fresh disinfection solution ~~should~~ must be made daily or if visibly soiled.

Preparation table:

Dilution	Preparation Method
1:400	1/3 fluid ounce per gallon of water
1:256	1/2 fluid ounce per gallon of water
1:200	2/3 fluid ounce per gallon of water

† See organism and preparation table to determine the appropriate disinfection solution.

Sanitizing hatchery rooms, incubators and hatchers, poultry houses and livestock buildings by fogging:

A. **Hatchery rooms:**
Close room off so fog is confined to room to be treated. Prepare a stock solution of one (1) part VIROCID to four (4) parts water (25 fluid ounce VIROCID to 100 fluid ounce water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yard. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment.
Note: The generated fog is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after the actual fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt, sleeves, and pants.

B. Incubators and hatchers:
Prepare a stock solution of one (1) part of VIROCID to four (4) parts water. Fog 3 ounces of solution per ~~for~~ 100 cubic feet ~~of this~~ into setters and hatchers immediately after transfer. Repeat daily. Discontinue hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has settled (30-60 minutes after fogging is completed). To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog.
It is also satisfactory to fog setters and hatchers with a 1:1000 solution of VIROCID. If this is done, fog for 30-90 seconds once per hour or once every two hours.

C. Poultry houses and livestock buildings:
After the house has been depopulated and cleaned as in 1. A to F under "Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment", double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as tight as possible.
Prepare a stock solution of one (1) part VIROCID to four (4) parts water (25 fluid ounce VIROCID to 100 fluid ounce water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yard. Place the fogger ~~itself may be placed~~ just inside the door of the building to be treated, or insert ~~the~~ nozzle of the fogger ~~may be inserted~~ through a suitable opening in the door or building. The opening must ~~should~~ be just large enough to accommodate the nozzle.
After fogging, the building must ~~should~~ be kept closed for twenty-four hours. After twenty-four hours, ~~the fog should have settled and~~ open the house ~~can now be opened~~ and air~~ed. The house should be opened~~ for a minimum of twenty-four hours before it is repopulated with poultry or livestock.
Note: The generated fog is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completed settled, normally 1-4 hours after the actual fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt, sleeves and pants.
If feeders and waterers were not removed from the premise during treatment, or were not adequately covered to prevent contact with treatment, they must ~~should~~ be washed with detergent and water before use for poultry or livestock.

Control of algae and slime forming bacteria in recirculating water cooling systems and evaporative condensers:

A. VIROCID must ~~should~~ be added in the system directly at a point where uniform mixing and even distribution will occur Do ~~and~~ not mix~~ed~~ with any other chemicals or additives.~~; it should be added~~
B. Severely fouled systems must ~~should~~ be chemically and/or manually cleaned before adding VIROCID treatment. If algae/slime growth is absent or minimal, proceed with the initial dose.
C. Initial Dose: 2.5 fluid ounces of VIROCID per 100 gallons of water (50 ppm) in the system. Repeat treatment until algae/slime growth is controlled.
Maintenance Dose: After algae control is evident/achieved, apply 1.25 fluid ounces of VIROCID per 100 gallons of water (25 ppm) in the system every 7 days (weekly). Repeat treatment as needed to maintain algae/slime control.

STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal
Storage: Store in a cool, dry place in tightly closed container away from children. Avoid temperatures below 23°F and above 113°F.
Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance.
Container Disposal: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. *{Insert applicable triple rinse instruction for container size below}* Offer for recycling if available. ~~Triple rinse. Then offer for recycling or puncture and dispose in a sanitary landfill. Disposal by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.~~

Note: Bracketed[ ]information is optional text. Text separated by a comma(,)denotes-and/or-options. {Bracketed Text}Is for administrative purposes only and will not appear on the printed label.

(For containers equal to or less than 5 gallons)
Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.
(For containers greater than 5 gallons)
Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container over on its end and tip it back and forth several times. Empty rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

PRECAUTIONARY STATEMENTS:

Hazards to humans and domestic animals
DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if absorbed through ~~the~~ skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves. Harmful if inhaled. Avoid breathing vapor. Harmful if swallowed. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.
Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, ~~or~~ using tobacco, or using the toilet. ~~Remove contaminated clothing and wash before reuse.~~ Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS:

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact our State Water Board or Regional Office of the EPA.

LIMITED WARRANTY AND DISCLAIMER:
The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is a reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warnings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warnings or cautions. Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, whether or not such liability is based in the contract, negligence, strict liability in tort of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.

EPA Reg. No. 71355-1 EPA Est. No. 71355-BEL-001
Batch No: See top/bottom
Expiry Date: See top/bottom
Net Contents: See top/bottom

(net contents will appear on front panel; registration numbers, batch no. and expiry date may appear on any panel)

CID LINES
INNOVATIVE HYGIENE SOLUTIONS

Produced by :
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VIROCID®

CONCENTRATED BROAD SPECTRUM DISINFECTANT

Active ingredients :

ALKYL* DIMETHYL BENZYL AMMONIUM CHLORIDE *(50% C14;40% C12;10% C16)	17.060 % (by wt)
DIDECYL DIMETHYL AMMONIUM CHLORIDE	7.800 %
GLUTARALDEHYDE	10.725 %
Inert ingredients	64.415 %
	100.000 %

KEEP OUT OF REACH OF CHILDREN

DANGER

VIROCID is effective against :

BACTERIA	Dilution
*Salmonella Choleraesuis (ATCC 10708)**	1:400
*Staphylococcus aureus (ATCC 6538)**	1:400
*Pseudomonas aeruginosa (ATCC 15442)**	1:400
[redacted]	1:400
	1:400
	1:400
	1:400
	1:400
	1:400
	1:400
	1:400
	1:400
*Mycoplasma hyopneumoniae (ATCC 25934)**	1:400
*Streptococcus suis (ATCC 43765)**	1:400
*Salmonella choleraesuis subsp. Choleraesuis, serotype typhisuis (ATCC 8321)**	1:400
*Escherichia coli (ATCC 11229)**	1:400
[redacted]	1:256
	1:256
FUNGUS *(on environmental surfaces)*	
[redacted]	1:400
	1:400
Trichophyton mentagrophytes (ATCC 9533)	1:400
VIRUS *(on environmental surfaces)* :	
*Porcine circovirus, type II (PCV, PT-1 cell)**	1:200
*Pseudorabies (American BioResearch Laboratories)**	1:400
*Porcine Respiratory and Reproductive Syndrome (Arko Laboratories)**	1:400
*Avian Reovirus (Spafas Strain)**	1:256
*Marek's Disease (Spafas Strain)**	1:400
*Newcastle Disease (Spafas Strain)**	1:400
*Avian Influenza (Turkey/Wis/66 strain – H9N2)**	1:400
*Avian Infectious Laryngotracheitis (Charles River laboratories)**	1:400
*Infectious Bursal Disease of Chickens (SPAFAS Strain 2512)**	1:400
Algae and slime forming bacteria in recirculating water cooling systems and evaporative condensers	25-50 ppm

**In the presence of 400 ppm AOAC synthetic hard water and 5% soil load*

ACCEPTED
with COMMENTS
In EPA Letter Dated:
APR 7 2005

Under the Pesticide
Registration
Number

71355-1

D. Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and rinse with potable water before reuse.
E. Disinfection of equipment : Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure in the appropriate disinfection solution* for 10 minutes. Allow to air dry.
F Fresh disinfection solution should be made daily.

2. Hatcheries :
Remove all animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, cans, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with the appropriate disinfection solution* by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed or dried. Fresh disinfection solution should be made daily or if visibly soiled.

3. Food processing plants (including Chicken Processing Facilities) :
Before using this product, all food products and packaging materials must be removed from the room or carefully protected. Thoroughly clean all surfaces with soap or detergent, then rinse with water. Disinfect hard, non-porous surfaces by applying the appropriate disinfection solution* with a coarse spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

4. Trucks and other vehicles :
Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the appropriate disinfection solution* to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

5. Veterinary hospitals :
For disinfection of the following hard non-porous surfaces : floors, walls, ceilings, counters, cages, feeding/drinking equipment, and handling/restraining equipment. Remove animals and feed from the premises. Thoroughly clean all surfaces with soap or detergent, then rinse with water. Saturate surfaces with the appropriate disinfection solution* by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Immerse all leashes, muzzles, ropes or other types of equipment used to restrain or handle animals as well as shovels, scrapers, and forks used to remove manure and litter. Do not house livestock or employ equipment until surfaces have been absorbed or dried. Thoroughly scrub treated feeding and watering equipment with soap or detergent and rinse with potable water before reuse. Fresh disinfection solution should be made daily or if visibly soiled.

Preparation table :

dilution	*Preparation method*
1:1000	
1:400	⅛ fluid ounce per gallon of water
1:256	½ fluid ounce per gallon of water
1:200	⅔ fluid ounce per gallon of water

APR 7 2005

71355 1

Sanitizing hatchery rooms, incubators and hatchers, poultry houses and livestock buildings by fogging

A. Hatchery rooms
Close room off so fog is confined to room to be treated. Prepare a stock solution of one (1) part VIROCID to four (4) parts water (25 fluid ounce VIROCID to 100 fluid ounce water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yard. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment. *Note* : The generated fog is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after the actual fogging. If the building or room must be entered, then the individuals

STORAGE AND DISPOSAL :

Do not contaminate water, food, or feed by storage and disposal
Storage : Store in a cool, dry place in tightly closed container away from children. Avoid temperatures below 23°F and above 113°F.
Disposal of pesticide : Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance.
Disposal of container : Triple rinse. Then offer for recycling or puncture and dispose in a sanitary landfill. Disposal by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

ENVIRONMENTAL HAZARDS :

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PRECAUTIONARY STATEMENTS

Hazard to humans and domestic animals
DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves. Harmful if inhaled. Avoid breathing vapor. Harmful if swallowed. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.
Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash before reuse.

LIMITED WARRANTY AND DISCLAIMER :

The manufacturer warrants (a) that this product conforms to the chemical description on the label ; (b) that this product is a reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions ; and (c) that the directions, warnings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warnings or cautions. Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, whether or not such liability is based in the contract, negligence, strict liability in tort of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.

EPA Reg. N° 71355-1 EPA Est. N° : 71355-BEL-001
BATCH N° : see top / bottom EXPIRY DATE : see top / bottom
Net contents : see top / bottom

Produced by :
CID LINES NV/SA - Waterpoortstraat 2 - B 8900 IEPER - BELGIUM - EUROPE
Phone: 011-32-57-217877 - Fax: 011-32-57-217879
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CID LINES

APR 7 2005

71355-1

SRC
Scientific & Regulatory
Consultants, Inc.

July 30, 2010

Velma Noble, PM 31
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

SUBJECT: VIROCID
EPA Reg. No. 71355-1

Dear Velma,

On behalf of CID LINES NV/SA is an amendment with data for Virocid. This amendment is a PRIA action code A570 which is assigned a PRIA fee of $3308 and a 4 month review time. A copy of the confirmation of payment via www.pay.gov is attached.

The purpose of the submission is to:

- Add new claims for Human Influenza A virus (H1N1) and Swine Influenza A virus (H1N1). (See Volumes 3 – 4.)
- Add data previously rejected[1] to support
  - *Mycoplasma gollisepticum*[2],
  - *Mycoplasma synoviae*,
  - *Bordetella avium*,
  - *Klebsiella pneumoniae*,
  - *Ornithabacterium rhinatracheale*,
  - *Salmonella enterica (formerly S. enteritidis)*,
  - *Salmonella enterica (formerly S. cholerasuis, serotype typhisuis)*
  - *Salmonella enterica (formerly S. pullorum)*,
  - *Campylobacter jejuni*,
  - *Corynebacterium pseudatuberculosis*,
  - *Avibacterium paragellinarum (formerly H. paragallinarum)*,
  - *Listeria monocytogenes*,
  - *Fusarium dimerum*, and
  - *Penicillium expansum*

[1] The studies for these organisms were assigned MRID 46049901 and 46049902. Rationale for accepting this data was provided to Tajah Black prior to filing this submission. Volume 2 of this submission provides justification for accepting this data.
[2] Strain designates (e.g. ATCC) are provided on enclosed data matrix.

P.O. Box 1014
Columbia City, IN 46725
www.srcconsultants.com
Phone: 260-244-6270
Fax: 260-244-6273

- Upgraded the
  - first aid statements, to comply with PR Notice 2001-1,
  - precautionary statements to comply with the Labeling Review Manual Chapter 8, and
  - storage and disposal language to reflect the Container and Containment Review per PR Notice 2007-4.

Enclosed are 5 copies of labeling with the changes and deletions reflected. An electronic label named "071355-00001.2010728.Amend.pdf" is attached which incorporates all changes in proper electronic label format.

The CSF has been updated to reflect a change in ownership of the registered active ingredient, glutaraldehyde. [redacted] is now under the ownership of [redacted] requiring a change in the EPA registered active number from [redacted] to [redacted]. In addition, the [redacted] listed in Column 13 was corrected to reflect the total product weight as 100% by weight. This replaces the CSF dated 06/10/98.

Please contact me at (260) 244-6270 or shayes@srcconsultants.com if you have any questions regarding this submission.

Sincerely,

Sally Hayes
Agent, CID LINES NV/5A

cc: A. Francois, CID LINES

VIROCID

EPA Registration No: 71355-1

TRANSMITTAL DOCUMENT

1. Name and address of submitter:
   Scientific & Regulatory Consultants, Inc.
   PO Box 1014
   Columbia City, IN 46725

   AGENT FOR:
   CID LINES NV/SA
   Waterpoortstraat 2
   B 8900 IEPER BELGIUM

2. Regulatory action in support of which this package is submitted:
   AMENDMENT: PRIA Code A570, PRIA fee $3308

3. Transmittal date:
   July 30, 2010

4. Vol. 1 Administrative materials:
   A) Cover letter
   B) Copy of Agent Authorization
   C) Copy of PRIA II payment ($3308 for AS70 Initial Registration)
   D) Application
   E) Certification with Respect to Citation of Data
   F) Data Matrix
   G) Formulator's Exemption Statement
   H) CSF dated 06/10/98
   I) 2 copies of revised CSF dated 07/28/10
   J) 1 copy of label with changes highlighted and deletions shown
   K) 5 copies of label without highlighting or deletions
   L) Electronic label 071355-00001.2D100728.Amend.pdf

5. Vol. 2 Efficacy

48174201 A) Efficacy Discussion

6. Vol. 3 Efficacy

48174202 A) Guideline 91-2 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Human Influenza A (H1N1) (A07937)

7. Vol. 4 Efficacy

48174203 A) Guideline 91-2 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Swine Influenza A (H1N1) (A07938)

Company Official:	Sally Hayes
Company Name:	Agent for CID LINES NV/SA
Company Contact:	Sally Hayes Phone: 260-244-6270 E-mail: shayes@srcconsultants.com

E. Disinfection of equipment: Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure in the appropriate disinfection solution† for 10 minutes. Allow to air dry.
F. Fresh disinfection solution should be made daily or if visibly soiled.

2. **Hatcheries:**
Remove all animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, carts, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with the appropriate disinfection solution† by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed or dried. Fresh disinfection solution ~~should~~ must be made daily or if visibly soiled.

3. **Food processing plants (including Chicken Processing Facilities):**
Before using this product, all food products and packaging materials must be removed from the room or carefully protected. Thoroughly clean all surfaces with soap or detergent, then rinse with water. Disinfect hard, non-porous surfaces by applying the appropriate disinfection solution† with a coarse spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

4. **Trucks and other vehicles:**
Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the appropriate disinfection solution† to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

5. **Veterinary hospitals:**
For disinfection of the following hard non-porous surfaces: floors, walls, ceilings, counters, cages, feeding/drinking equipment, and handling/restraining equipment. Remove animals and feed from the premises. Thoroughly clean all surfaces with soap or detergent, then rinse with water. Saturate surfaces with the appropriate disinfection solution† by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Immerse all leashes, muzzles, ropes or other types of equipment used to restrain or handle animals as well as shovels, scrapers, and forks used to remove manure and litter. Do not house livestock or employ equipment until surfaces have been absorbed or dried. Thoroughly scrub treated feeding and watering equipment with soap or detergent and rinse with potable water before reuse. Fresh disinfection solution ~~should~~ must be made daily or if visibly soiled.

Preparation table:

Dilution	Preparation Method
1:400	1/3 fluid ounce per gallon of water
1:256	1/2 fluid ounce per gallon of water
1:200	2/3 fluid ounce per gallon of water

† See organism and preparation table to determine the appropriate disinfection solution.

adjust

Sanitizing hatchery rooms, incubators and hatchers, poultry houses and livestock buildings by fogging:

A. Hatchery rooms:
Close room off so fog is confined to room to be treated. Prepare a stock solution of one (1) part VIROCID to four (4) parts water (25 fluid ounce VIROCID to 100 fluid ounce water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yard. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment.
Note: The generated fog is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after the actual fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt, sleeves, and pants.

B. Incubators and hatchers:
Prepare a stock solution of one (1) part of VIROCID to four (4) parts water. Fog 3 ounces of solution per ~~for~~ 100 cubic feet ~~of this~~ into setters and hatchers immediately after transfer. Repeat daily. Discontinue hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has settled (30-60 minutes after fogging is completed). To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog.
It is also satisfactory to fog setters and hatchers with a 1:1000 solution of VIROCID. If this is done, fog for 30-90 seconds once per hour or once every two hours.

C. Poultry houses and livestock buildings:
After the house has been depopulated and cleaned as in 1. A to F under "Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment", double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as tight as possible.
Prepare a stock solution of one (1) part VIROCID to four (4) parts water (25 fluid ounce VIROCID to 100 fluid ounce water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yard. Place the fogger ~~itself may be placed~~ just inside the door of the building to be treated, or insert ~~the~~ nozzle of the fogger ~~may be inserted~~ through a suitable opening in the door or building. The opening must ~~should~~ be just large enough to accommodate the nozzle.
After fogging, the building must ~~should~~ be kept closed for twenty-four hours. After twenty-four hours, ~~the fog should have settled and~~ open the house ~~can now be opened~~ and aired~~. The house should be opened~~ for a minimum of twenty-four hours before it is repopulated with poultry or livestock.
Note: The generated fog is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completed settled, normally 1-4 hours after the actual fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt, sleeves and pants.
If feeders and waterers were not removed from the premise during treatment, or were not adequately covered to prevent contact with treatment, they must ~~should~~ be washed with detergent and water before use for poultry or livestock.

Control of algae and slime forming bacteria in recirculating water cooling systems and evaporative condensers:

A. VIROCID must ~~should~~ be added in the system directly at a point where uniform mixing and even distribution will occur. Do ~~and~~ not mixed with any other chemicals or additives.~~; it should be added~~
B. Severely fouled systems must ~~should~~ be chemically and/or manually cleaned before adding VIROCID treatment. If algae/slime growth is absent or minimal, proceed with the initial dose.
C. Initial Dose: 2.5 fluid ounces of VIROCID per 100 gallons of water (50 ppm) in the system. Repeat treatment until algae/slime growth is controlled.
Maintenance Dose: After algae control is evident/achieved, apply 1.25 fluid ounces of VIROCID per 100 gallons of water (25 ppm) in the system every 7 days (weekly). Repeat treatment as needed to maintain algae/slime control.

STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal
Storage: Store in a cool, dry place in tightly closed container away from children. Avoid temperatures below 23°F and above 113°F.
Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance.
Container Disposal: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. *{Insert applicable triple rinse instruction for container size below}* Offer for recycling if available. ~~Triple rinse. Then offer for recycling or puncture and dispose in a sanitary landfill. Disposal by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.~~

(For containers equal to or less than 5 gallons)
Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.
(For containers greater than 5 gallons)
Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container over on its end and tip it back and forth several times. Empty rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

PRECAUTIONARY STATEMENTS:

Hazards to humans and domestic animals
DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if absorbed through ~~the~~ skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves. Harmful if inhaled. Avoid breathing vapor. Harmful if swallowed. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.
Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, ~~or~~ using tobacco, or using the toilet. ~~Remove contaminated clothing and wash before reuse.~~ Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS:

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact our State Water Board or Regional Office of the EPA.

LIMITED WARRANTY AND DISCLAIMER:
The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is a reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warnings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warnings or cautions. Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, whether or not such liability is based in the contract, negligence, strict liability in tort or otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.

EPA Reg. No. 71355-1 EPA Est. No. 71355-BEL-001
Batch No: See top/bottom
Expiry Date: See top/bottom
Net Contents: See top/bottom

(net contents will appear on front panel; registration numbers, batch no. and expiry date may appear on any panel)

CID LINES®
INNOVATIVE HYGIENE SOLUTIONS

Produced by :
CID LINES NV/SA
Waterpoortstraat 2 – B 8900 IEPER
BELGIUM – EURDPE
Phone : 011 32 57 217877
Fax : 011 32 57 217879
www.cidlines.com - info@cidlines.com

Note: Bracketed[ ]information is optional text. Text separated by a comma(,)denotes–and/or-options. {Bracketed Text}is for administrative purposes only and will not appear on the printed label.

VIROCID®

CONCENTRATED BROAD SPECTRUM DISINFECTANT

Active Ingredients :

ALKYL* DIMETHYL BENZYL AMMONIUM CHLORIDE *(50% C14;40% C12;10% C16)	17.060 % (by wt)
DIDECYL DIMETHYL AMMONIUM CHLORIDE	7.800 %
GLUTARALDEHYDE	10.725 %
Inert Ingredients	64.415 %
	100.000 %

KEEP OUT OF REACH OF CHILDREN

DANGER

VIROCID is effective against :

BACTERIA	Dilution
*Salmonella Choleraesuis (ATCC 10708)**	1:400
*Staphylococcus aureus (ATCC 6538)**	1:400
*Pseudomonas aeruginosa (ATCC 15442)**	1:400
[redacted]	1:400
[redacted]	1:400
[redacted]	1:400
[redacted]	1:400
[redacted]	1:400
[redacted]	1:400
[redacted]	1:400
[redacted]	1:400
[redacted]	1:400
[redacted]	1:400
*Mycoplasma hyopneumoniae (ATCC 25934)**	1:400
*Streptococcus suis (ATCC 43765)**	1:400
*Salmonella cholerasuis subsp. Cholerasuis, serotype typhisuis (ATCC 8321)**	1:400
*Escherichia coli (ATCC 11229)**	1:400
[redacted]	1:256
[redacted]	1:256
FUNGUS *(on environmental surfaces)* :	
[redacted]	1:400
[redacted]	1:400
Tricophyton mentagrophytes (ATCC 9533)	1:400
VIRUS *(on environmental surfaces)* :	
*Porcine circovirus, type II (PCV, PT-1 cell)**	1:200
*Pseudorabies (American BioResearch Laboratories)**	1:400
*Porcine Respiratory and Reproductive Syndrome (Arko Laboratories)**	1:400
*Avian Reovirus (Spafas Strain)**	1:256
*Marek's Disease (Spafas Strain)**	1:400
*Newcastle Disease (Spafas Strain)**	1:400
*Avian Influenza (Turkey/Wis/66 strain – H9N2)**	1:400
*Avian Infectious Laryngotracheitis (Charles River laboratories)**	1:400
*Infectious Bursal Disease of Chickens (SPAFAS Strain 2512)**	1:400
Algae and slime forming bacteria in recirculating water cooling systems and evaporative condensers	25-50 ppm

**in the presence of 400 ppm AOAC synthetic hard water and 5% soil load*

ACCEPTED
with COMMENTS
in EPA Letter Dated:
APR 7 2005

71355-1

FIRST AID STATEMENTS	
Have product container with you when calling the poison control center, doctor, or going for medical treatment.	
IF IN EYES	• Hold eyelids open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF INHALED	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth- to- mouth, if possible. • Call a poison control center or doctor for further treatment advice.
NOTE TO PHYSICIAN :	
Probable mucosal damage may contraindicate the use of gastric lavage.	

APPLICATION :

Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment :

1. *Farm Equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings)*
2. *Hatchers, Setters, and chick processing facilities*
3. *Food processing plants (slaughterhouses)*
4. *Trucks and other vehicles*
5. *Veterinary hospitals.*

Sanitizing hatchery rooms, incubators and hatchers, poultry houses and livestock buildings by fogging.

Control of algae and slime forming bacteria in recirculating water cooling systems and evaporative condensers.

DIRECTIONS FOR USE :

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment :

1. Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings) :

For disinfection of hard, non-porous surfaces : stainless, galvanized and painted steel, copper, aluminum, finished wood, vinyl, plastics, glazed tiles, sealed brick walls, aluminium sandwich panels and feeding/drinking equipment :

A. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
B. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with the appropriate disinfection solution* by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
C. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried.

* see table top of label to determine the appropriate disinfection solution

APR 7 2005

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D. Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and rinse with potable water before reuse.
E. Disinfection of equipment : Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure in the appropriate disinfection solution* for 10 minutes. Allow to air dry.
F. Fresh disinfection solution should be made daily.

2. Hatcheries :
Remove all animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, carts, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with the appropriate disinfection solution* by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed or dried. Fresh disinfection solution should be made daily or if visibly soiled.

3. Food processing plants (including Chicken Processing Facilities) :
Before using this product, all food products and packaging materials must be removed from the room or carefully protected. Thoroughly clean all surfaces with soap or detergent, then rinse with water. Disinfect hard, non-porous surfaces by applying the appropriate disinfection solution* with a coarse spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

4. Trucks and other vehicles :
Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the appropriate disinfection solution* to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

5. Veterinary hospitals :
For disinfection of the following hard non-porous surfaces : floors, walls, ceilings, counters, cages, feeding/drinking equipment, and handling/restraining equipment. Remove animals and feed from the premises. Thoroughly clean all surfaces with soap or detergent, then rinse with water. Saturate surfaces with the appropriate disinfection solution* by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Immerse all leashes, muzzles, ropes or other types of equipment used to restrain or handle animals as well as shovels, scrapers, and forks used to remove manure and litter. Do not house livestock or employ equipment until surfaces have been absorbed or dried. Thoroughly scrub treated feeding and watering equipment with soap or detergent and rinse with potable water before reuse. Fresh disinfection solution should be made daily or if visibly soiled.

Preparation table :

dilution	*Preparation method*
1:1000	
1:400	⅛ fluid ounce per gallon of water
1:256	½ fluid ounce per gallon of water
1:200	⅝ fluid ounce per gallon of water

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<u>Sanitizing hatchery rooms, incubators and hatchers, poultry houses and livestock buildings by fogging</u>

A. Hatchery rooms :
Close room off so fog is confined to room to be treated. Prepare a stock solution of one (1) part VIROCID to four (4) parts water (25 fluid ounce VIROCID to 100 fluid ounce water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yard. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment.
Note : The generated fog is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after the actual fogging. If the building or room must be entered, then the individuals

entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt, sleeves and pants.

B. Incubators and hatchers :
Prepare a stock solution of one (1) part VIROCID to four (4) parts water. Fog 3 ounces for 100 cubic feet of this into setters and hatchers immediately after transfer. Repeat daily. Discontinue hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has settled (30-60 minutes after fogging is completed) To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog.
It is also satisfactory to fog setters and hatchers with a 1:1000 solution of VIROCID. If this is done, fog for 30-90 seconds once per hour or once every two hours.

C. Poultry houses and livestock buildings :
After the house has been depopulated and cleaned as in 1. A to F under "Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment", double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as tight as possible. Prepare a stock solution of one (1) part VIROCID to four (4) parts water (25 fluid ounce VIROCID to 100 fluid ounce water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yard. The fogger itself may be placed just inside the door of the building to be treated, or the nozzle of the fogger may be inserted through a suitable opening in the door or building. The opening should be just large enough to accommodate the nozzle. After fogging, the building should be kept closed for twenty-four hours. After twenty-four hours, the fog should have settled and the house can now be opened and aired. The house should be opened for a minimum of twenty-four hours before it is repopulated with poultry or livestock.
Note : The generated fog is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after the actual fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt, sleeves and pants. If feeders and waterers were not removed from the premise during treatment, or were not adequately covered to prevent contact with treatment, they should be washed with detergent and water before use for poultry or livestock.

<u>Control of algae and slime forming bacteria in recirculating water cooling systems and evaporative condensers</u>

A. VIROCID should be added in the system directly and not mixed with any other chemicals or additives : it should be added at a point where uniform mixing and even distribution will occur.
B. Severely fouled systems should be chemically and/or manually cleaned before adding VIROCID treatment. If Algae/slime growth is absent or minimal, proceed with the initial dose.
C. Initial Dose 2.5 fluid ounces of VIROCID per 100 gallons of water (50ppm) in the system. Repeat treatment until algae/slime growth is controlled. **Maintenance Dose :** After algae control is evident/achieved, apply 1.25 fluid ounces of VIROCID per 100 gallons of water (25ppm) in the system every 7 days (weekly). Repeat treatment as needed to maintain algae/slime control.

ACCEPTED
with COMMENTS
In EPA letter Dated:
APR 7 2005

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No 71355-1

STORAGE AND DISPOSAL :

Do not contaminate water, food, or feed by storage and disposal
Storage : Store in a cool, dry place in tightly closed container away from children. Avoid temperatures below 23°F and above 113°F.
Disposal of pesticide : Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance.
Disposal of container : Triple rinse. Then offer for recycling or puncture and dispose in a sanitary landfill. Disposal by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

ENVIRONMENTAL HAZARDS :

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PRECAUTIONARY STATEMENTS

Hazard to humans and domestic animals
DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves. Harmful if inhaled. Avoid breathing vapor. Harmful if swallowed. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.
Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash before reuse.

LIMITED WARRANTY AND DISCLAIMER :

The manufacturer warrants (a) that this product conforms to the chemical description on the label ; (b) that this product is a reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions ; and (c) that the directions, warnings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties of merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warnings or cautions. Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, whether or not such liability is based in the contract, negligence, strict liability in tort of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product

EPA Reg. N° : 71355-1 EPA Est. N° : 71355-BEL-001
BATCH N° : see top / bottom EXPIRY DATE : see top / bottom
Net contents : see top / bottom

Produced by :
CID LINES NV/SA - Waterpoortstraat 2 - B 8900 IEPER - BELGIUM - EUROPE
Phone: 011-32-57-217877 - Fax: 011-32-57-217879
http://www.cidlines.com - info@cidlines.com

CID LINES
INNOVATIVE HYGIENE SOLUTIONS

APR 7 2005

71355-1

Decision #: 438047
DP #: (381154)
PRIA
Parent DP #:
Submission #: 879635

DATA PACKAGE BEAN SHEET

Date: 16-Aug-2010

* * * Registration Information * * *

Registration: 71355-1 - VIROCID

Company: 71355 - CID LINES N.V.

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-6855

Risk Manager Reviewer: Cletis Mixon CMIXON

Sent Date: _____ Calculated Due Date: 23-Dec-2010 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A570) AMENDMENT;NON-FAST TRACK;

Ingredients: See page 3

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 16-Aug-2010 Due Back: _____

DP Ingredient: See page 3

DP Title: _____

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #: _____

120
90

Assigned To	Date In	Date Out	
Organization: AD / PSB	8/16/10		Last Possible Science Due Date: 23-Nov-2010
Team Name: EET	8/16/10		Science Due Date: 10/29/10
Reviewer Name: Ibrahim	8/17/10		Sub Data Package Due Date: 11/12/10
Contractor Name:			

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

Tajah -efficacy - Registrant has submitted efficacy data to be reviewed. MRID#s, 48174201, 48174202, 48174203.

RECEIVED 8/16/10

DP#: (381154) *** Studies Sent for Review *** Decision#: (438047)

MRID	MRID Status	Citation Reference	Guideline
48174203		Gulzmann, K. (2010) Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Swine Influenza A (H1N1) Virus: Virocide: Final Report. Project Number: A07938, SRC46042909/SFLU. Unpublished study prepared by ATS Labs. 27 p.	810.2100/Products for use on hard surfaces-basic efficacy data requirements
48174202		Gulzmann, K. (2009) Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Virocid: Human Influenza A (H1N1) Virus: Final Report. Project Number: A07937, SRC46043009/FLUA. Unpublished study prepared by ATS Labs. 29 p.	810.2100/Products for use on hard surfaces-basic efficacy data requirements
48174201		Jones, R. (2010) Virocid: Efficacy Discussion: (M. gallisepticum, M. synoviae, B. avium, K. pneumoniae, O. rhinotracheale, S. enterica, S. pullorum, C. jejuni, C. pseudotuberculosis, H. paragallinarum, L. monocytogenes, F. dimerum and P. expansum). Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 20 p.	810.2100/Products for use on hard surfaces-basic efficacy data requirements

Decision #: 438047
DP #: (381154)
PRIA
Parent DP #:
Submission #: 879635

DATA PACKAGE BEAN SHEET

Date: 09-Nov-2010

* * * Registration Information * * *

Registration: 71355-1 - VIROCID
Company: 71355 - CID LINES N.V.
Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-6855
Risk Manager Reviewer: Cletis Mixon CMIXON
Sent Date: _____ Calculated Due Date: 23-Dec-2010 Edited Due Date: _____
Type of Registration: Product Registration - Section 3
Action Desc: (A570) AMENDMENT;NON-FAST TRACK;
Ingredients: See page 3

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 16-Aug-2010 Due Back: _____
DP Ingredient: See page 3

DP Title: _____
CSF Included: ◯ Yes ● No Label Included: ◯ Yes ● No Parent DP #: _____

Assigned To		Date In	Date Out		
Organization:	AD / PSB	16-Aug-2010		Last Possible Science Due Date:	23-Nov-2010
Team Name:	EET	16-Aug-2010		Science Due Date:	29-Oct-2010
Reviewer Name:	Laniyan, Ibrahim	17-Aug-2010	30-Nov-2009	Sub Data Package Due Date:	12-Nov-2010
Contractor Name:					

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

Tajah -efficacy - Registrant has submitted efficacy data to be reviewed. MRID#s, 48174201, 48174202, 48174203.

DP#: (381154) *** Studies Sent for Review *** Decision#: (438047)

MRID	MRID Status	Citation Reference	Guideline
48174201	Acceptable	Jones, R. (2010) Virocid: Efficacy Discussion: (M. gallisepticum, M. synoviae, B. avium, K. pneumoniae, O. rhinotracheale, S. enterica, S. pullorum, C. jejuni, C. pseudotuberculosis, H. paragallinarum, L. monocytogenes, F. dimerum and P. expansum). Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 20 p.	810.2100/Products for use on hard surfaces-basic efficacy data requirements
48174202	Acceptable	Gutzmann, K. (2009) Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Virocid: Human Influenza A (H1N1) Virus: Final Report. Project Number: A07937, SRC46043009/FLUA. Unpublished study prepared by ATS Labs. 29 p.	810.2100/Products for use on hard surfaces-basic efficacy data requirements
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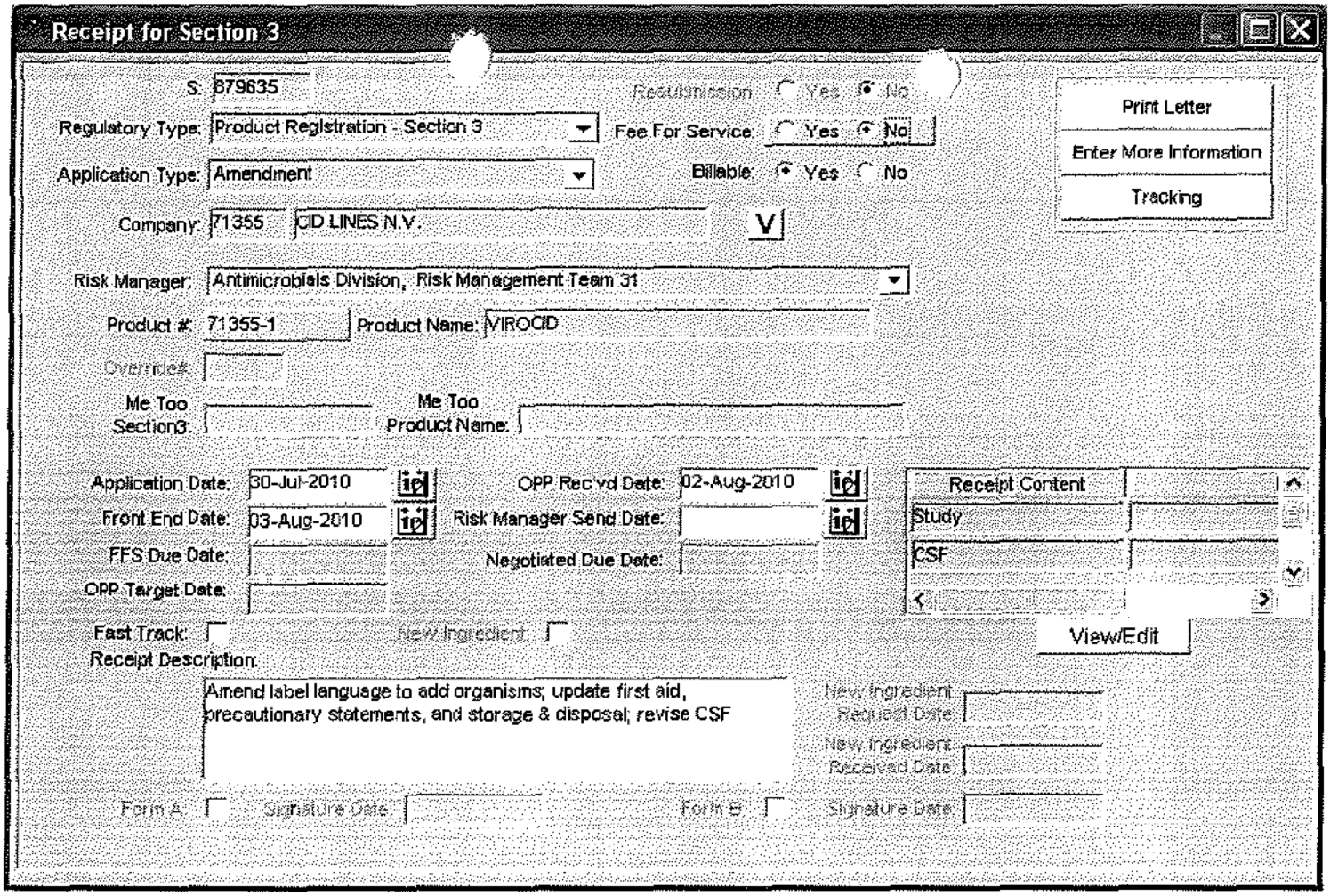
DP#: (381154) *** Product Data Package Ingredients *** Decision#: (438047)

PC Code	CAS	Ingredient Name
043901	111-30-8	Glutaraldehyde
069105	68424-85-1	Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16)
069149	7173-51-5	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride
043901	111-30-8	Glutaraldehyde(10.725%)
069105	68424-85-1	Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16)(17.06%)
069149	7173-51-5	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride(7.8%)


Receipt for Section 3
S: 879635
Resubmission: Yes No
Print Letter
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Enter More Information
Application Type: Amendment
Billable: Yes No
Tracking
Company: 71355 CID LINES N.V.
Risk Manager: Antimicrobials Division, Risk Management Team 31
Product #: 71355-1
Product Name: VIROCID
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 30-Jul-2010
OPP Rec'vd Date: 02-Aug-2010
Front End Date: 03-Aug-2010
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Amend label language to add organisms; update first aid, precautionary statements, and storage & disposal; revise CSF
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

SRC
Scientific & Regulatory
Consultants, Inc.

July 30, 2010

Velma Noble, PM 31
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

SUBJECT: VIROCID
EPA Reg. No. 71355-1

Dear Velma,

On behalf of CID LINES NV/SA is an amendment with data for Virocid. This amendment is a PRIA action code AS70 which is assigned a PRIA fee of $3308 and a 4 month review time. A copy of the confirmation of payment via www.pay.gov is attached.

The purpose of the submission is to:

- Add new claims for Human Influenza A virus (H1N1) and Swine Influenza A virus (H1N1). (See Volumes 3 – 4.)
- Add data previously rejected[1] to support
  - *Mycaplasma gallisepticum*[2],
  - *Mycoplasma synaviae*,
  - *Bordetella avium*,
  - *Klebsiella pneumoniae*,
  - *Ornithobacterium rhinotracheale*,
  - *Salmonella enterica (formerly S. enteritidis)*,
  - *Salmonella enterica (farmerly S. cholerasuis, serotype typhisuis)*
  - *Salmonella enterica (farmerly S. pullarum)*,
  - *Campylabacter jejuni*,
  - *Corynebacterium pseudotuberculosis*,
  - *Avibacterium paragellinarum (formerly H. paragallinarum)*,
  - *Listerio monacytagenes*,
  - *Fusarium dimerum*, and
  - *Pencillium expansum*

[1] The studies for these organisms were assigned MRID 46049901 and 46049902. Rationale for accepting this data was provided to Tajah Black prior to filing this submission. Volume 2 of this submission provides justification for accepting this data.

[2] Strain designates (e.g. ATCC) are provided on enclosed data matrix.

P.O. Box 1014
Columbia City, IN 46725
www.srcconsultants.com
Phone: 260-244-6270
Fax: 260-244-6273

Inert ingredient information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

- Upgraded the
  - first aid statements, to comply with PR Notice 2001-1,
  - precautionary statements to comply with the Labeling Review Manual Chapter 8, and
  - storage and disposal language to reflect the Container and Containment Review per PR Notice 2007-4.

Enclosed are 5 copies of labeling with the changes and deletions reflected. An electronic label named "071355-00001.2010728.Amend.pdf" is attached which incorporates all changes in proper electronic label format.

The CSF has been updated to reflect a change in ownership of the registered active ingredient, glutaraldehyde. [redacted] is now under the ownership of [redacted] requiring a change in the EPA registered active number from [redacted] to [redacted]. In addition, the [redacted]r listed in Column 13 was corrected to reflect the total product weight as 100% by weight. This replaces the CSF dated 06/10/98.

Please contact me at (260) 244-6270 or shayes@srcconsultants.com if you have any questions regarding this submission.

Sincerely,

Sally Hayes
Agent, CID LINES NV/SA

cc: A. Francois, CID LINES

VIROCID

EPA Registration No: 71355-1

TRANSMITTAL DOCUMENT

1. Name and address of submitter:
   Scientific & Regulatory Consultants, Inc.
   PO Box 1014
   Columbia City, IN 46725

   AGENT FOR:
   CID LINES NV/SA
   Waterpoortstraat 2
   B 8900 IEPER BELGIUM

2. Regulatory action in support of which this package is submitted:
   AMENDMENT: PRIA Code AS70, PRIA fee $3308

3. Transmittal date:
   July 30, 2010

4. Vol. 1 Administrative materials:
   A) Cover letter
   B) Copy of Agent Authorization
   C) Copy of PRIA II payment ($3308 for A570 Initial Registration)
   D) Application
   E) Certification with Respect to Citation of Data
   F) Data Matrix
   G) Formulator's Exemption Statement
   H) CSF dated 06/10/98
   I) 2 copies of revised CSF dated 07/28/10
   J) 1 copy of label with changes highlighted and deletions shown
   K) 5 copies of label without highlighting or deletions
   L) Electronic label 71355-00001.20100728.Amend.pdf

5. Vol. 2 Efficacy

48174201 A) Efficacy Discussion

6. Vol. 3 Efficacy

48174202 A) Guideline 91-2 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Human Influenza A (H1N1) (A07937)

7. Vol. 4 Efficacy

48174203 A) Guideline 91-2 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Swine Influenza A (H1N1) (A07938)

Company Official:	Sally Hayes
Company Name:	Agent for CID LINES NV/SA
Company Contact:	Sally Hayes Phone: 260-244-6270 E-mail: shayes@srcconsultants.com

21-Day Screen of Amendment
(Completed by Contractor)

21-day Expires on 8-23-10

Document Part Of: 71355-1
MRID, If Any: 481742

Content Screen: Recommended to Pass/Fail

86-5 Review: Passed/Failed/NA

Document returned to:

Velma Noble

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 8-2-10

Experts In-Processing Signature: MF HARRINGTON Date 8-4-10 Fee Paid: Yes ✓

Division management contacted on issues No_____ Yes_____ Date_____

EPA Reg. Number: 71355-1	EPA Receipt Date: 8-2-10

	Items for Review	Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1)(link to form) signed & complete including package type	X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)	X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A) — yes: X; no:			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)	X		
	Certificate and data matrix consistent	X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B) — yes: ; no:			
	If applicable, is there a letter of Authorization for exclusive use only.			
4	**Formulator's Exemption Statement** (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)	X		
5	**Data Matrix** (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)	X		
	a) Selective Method (Fee category experts use) — yes: X; no:			
	b) Cite-All (Fee category experts use) — yes: ; no:			
	c) Applicant owns all data (Fee category experts use) — yes: ; no:			
6	**5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to** http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)	X		

7	**Is the data package consistent with PR Notice 86-5** (link to PRN 86-5)	X		
8	**Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)**			X
9	**If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)**			X
10	**Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

* All inerts approved for non food use.
* All the studies submitted along with this Submission has passed the PRN-86-5 Review.

Passed

AB

MRID 481742

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product** is **currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 4, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-438047
EPA File Symbol or Registration Number: 71355-1
Product Name: VIROCID
EPA Receipt Date: 02-Aug-2010
EPA Company Number: 71355
Company Name: CID LINES N.V.

SCIENTIFIC & REGULATORY CONSULTANT'S INC.
CID LINES N.V.
PO Box 1014
COLUMBIA CITY, IN 46725-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A570

AMENDMENT;NON-FAST TRACK;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,
Teresa Downs
Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{879635J~

This package includes the following

- ○ New Registration
- ◉ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 31

Receipt No. S-	879635
EPA File Symbol/Reg. No.	71355-1
Pin-Punch Date:	8/2/2010

☐ This item is NOT subject to FFS action.

Action Code:

Requested: A570

Granted: A570

Amount Due: $ 3305

Inerts cleared AB/08/05/10

Parent/Child Decisions:

☒ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: Team 2 Date: 8/3/10

Remarks:

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: AUG - 2 2010		EPA Reg. Number: 71355-1		
	Check List Item	Yes	No	N/A
1	Has the **PRIA Fee been Paid**; is a copy of the check or Pay.gov receipt included in the Submission Package?	X		
2	Is an **Application Form** (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	X		
3	Is a **Confidential Statement of Formula** (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	X		
4	Is a **Formulator's Exemption Statement** (EPA Form 8570-27) Included in the Submission Package?	X		
5	Is a **Certification with Respect to Citation of Data** (EPA Form 8570-34) Included in the Submission Package?	X		
6	Is a **Data Matrix** (EPA Form 8570-35) Included in the Submission Package?	X		
7	Is a **Label** Included in the Submission Package? CD	X		
8	Are **Data** included in the Submission Package?	X		
9	**Is the Submission an Amendment?**	X		

By order of / Opdrachtgever / Donneur d'ordre / Auftraggeber

NV CID LINES

WATERPOORTSTRAAT 2
8900 IEPER

10 FEB. 2010

BY ORDER OF OUR OFFICE IN GAND

REF. : [redacted]

U.S.Dollar

**********3.308,00**

DETAILS OF PAYMENT :
VIROCID PRIA AMENDM. PREPAYMENT

[redacted]
NV CID LINES

WATERPOORTSTRAAT 2
8900 IEPER

Mod. 2241ENFD

Please find herewith a cheque issued to your order. The present counterfoil may be torn off before presentation for payment.

U vindt, in bijlage, een aan uw order uitgegeven cheque. De onderstaande talon mag afgescheurd worden alvorens U de cheque voor betaling aanbiedt.

Veuillez trouver en annexe un chèque émis à votre ordre. Le présent talon peut être détaché avant de présenter le chèque pour le paiement.

Als Anlage finden Sie einen an Ihre Order ausgestellten Scheck. Der vorliegende Abschnitt kann abgetrennt werden, bevor Sie den Scheck zur Einlösung vorzeigen.

Yours truly - Hoogachtend - Salutations - Hochachtungsvoll

ING

C 095792

ING

Pay against this CHEQUE the sum of
Betaal tegen deze de som van
Payez contre ce la somme de
Zahlen Sie gegen diesen SCHECK die Summe von

WITHOUT CHARGES FOR BENEFICIARY

Amount/Bedrag/Montant/Betrag

U.S.Dollar **********3.308,00**

/**/*******
*/THREE THOUSAND THREE HUNDRED AND*******
/*EIGHT U.S.DOLLAR,00**********

ING Belgium SA/NV

Hermans Ludo

ING Belgium SA/NV

Leheuwe Michel

Fac-simile signatures / Fac-simile handtekeningen / Signatures fac-similées / Faksimile Unterschrift

N° 900020501 17336 GAND 05-02-10

To the order of / Aan de orde van / A l'ordre de / An die Order von

USEPA - WASHINGTON FINANCE CENTER
PO BOX 979074
ST LOUIS MO 63197-9000
USA

Drawee banker / Betrokkene bankier / Banquier tiré / Bezogener Bankier

[redacted]
BANK OF NEW YORK MELLON

1 WALL STREET 8TH FLOOR
NEW YORK NY 10286 USA
[redacted]

niet betaalbaar na 12 maanden vanaf datum van uitgifte
"nicht zahlbar nach 12 Monaten ab Ausstellungsdatum"

SRC
Scientific & Regulatory
Consultants, Inc.

July 30, 2010

Velma Noble, PM 31
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

SUBJECT: VIROCID
EPA Reg. No. 71355-1

Dear Velma,

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- Add data previously rejected[1] to support
  - *Mycoplasma gallisepticum*[2],
  - *Mycoplasma synoviae,*
  - *Bordetella avium,*
  - *Klebsiella pneumoniae,*
  - *Ornithobacterium rhinotracheale,*
  - *Salmonella enterica (formerly S. enteritidis),*
  - *Salmonella enterica (formerly S. cholerasuis, serotype typhisuis)*
  - *Salmonella enterica (formerly S. pullorum),*
  - *Campylobacter jejuni,*
  - *Corynebacterium pseudotuberculosis,*
  - *Avibacterium paragellinarum (formerly H. paragallinarum),*
  - *Listeria monocytogenes,*
  - *Fusarium dimerum,* and
  - *Pencillium expansum*

[1] The studies for these organisms were assigned MRID 46049901 and 46049902. Rationale for accepting this data was provided to Tajah Black prior to filing this submission. Volume 2 of this submission provides justification for accepting this data.

[2] Strain designates (e.g. ATCC) are provided on enclosed data matrix.

P.O. Box 1014
Columbia City, IN 46725
www.srcconsultants.com
Phone: 260-244-6270
Fax: 260-244-6273

Inert ingredient information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

- Upgraded the
  - first aid statements, to comply with PR Notice 2001-1,
  - precautionary statements to comply with the Labeling Review Manual Chapter 8, and
  - storage and disposal language to reflect the Container and Containment Review per PR Notice 2007-4.

Enclosed are 5 copies of labeling with the changes and deletions reflected. An electronic label named "071355-00001.2010728.Amend.pdf" is attached which incorporates all changes in proper electronic label format.

The CSF has been updated to reflect a change in ownership of the registered active ingredient, glutaraldehyde. [redacted] is now under the ownership of [redacted] requiring a change in the EPA registered active number from [redacted] to [redacted]. In addition, the [redacted] listed in Column 13 was corrected to reflect the total product weight as 100% by weight. This replaces the CSF dated 06/10/98.

Please contact me at (260) 244-6270 or shayes@srcconsultants.com if you have any questions regarding this submission.

Sincerely,

Sally Hayes
Agent, CID LINES NV/SA

cc: A. Francois, CID LINES

Product ingredient source information may be entitled to confidential treatment

Form Appr[illegible]. OMB No. 2070-0060. Approval Expires 5-31-98.

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
CID LINES NV/SA Waterpoortstraat 2 B 8900 IEPER BELGIUM	71355-t
	Product Name VIROCID
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* July 30, 2010

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

ALKYL *DIMETHYL BENZYL AMMONIUM CHLORIDE *(50% C14; 40% C12; 10% C16)
DIDECYL DIMETHYL AMMONIUM CHLORIDE
GLUTARALDEHYDE

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☑ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula)CSF) (EPA Form B570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
ALKYL *DIMETHYL BENZYL AMMONIUM CHLORIDE *(50% C14; 40% C12; 10% C16) DIDECYL DIMETHYL AMMONIUM CHLORIDE GLUTARALDEHYDE	[redacted]	

Signature	Name and Title	Date
	Sally Hayes, Agent for CID LINES NV/SA	July 30, 2010

Form 8570-27 (Rev. 8-95)

White - EPA copy
Yellow - Applicant copy

GPO: 1995-386-820/20413

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Cid Lines nv/sa, Waterpoortstraat 2- B8900 Ieper, Belgium	71355-1
Active Ingredient(s) and/or representative test compound(s) Alkyl* dimethylbenzyl ammonium chloride; Didecyl dimethyl ammonium chloride; Glutaraldehy	Date July 30, 2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Poultry and farm settings	Product Name VIROCID

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method, or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Sally Hayes	July 30, 2010	Sally Hayes, Agent for CID LINES NV/SA

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date July 30, 2010	EPA Reg No./File Symbol 71355-1	Page 1 of 8
Applicant's/Registrant's Name & Address CID LINES NV/SA Waterpoorstraat 2, 8900 IEPER, BELGIUM	Product VIROCID	

Ingredient Alkyl* dimethylbenzyl ammonium chloride (50% C_{14}, 40% C_{12}, 10% C_{16}); Didecyl dimethyl ammonium chloride; Glutaraldehyde

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.1550	Product Identity and Composition	44502201	CID LINES NV/SA		
OPPTS 830.1600	Description of Materials Used to Produce the Product	44502201	CID LINES NV/SA		
OPPTS 830.1620	Description of Production Process	44502201	CID LINES NV/SA		
OPPTS 830.1650	Description of Formulation Process	44502201	CID LINES NV/SA		
OPPTS 830.1670	Discussion of Formation of Impurities	44502201	CID LINES NV/SA		
OPPTS 830.1700	Preliminary Analysis	N/A	CID LINES NV/SA		[1]
OPPTS 830.1750	Certified Limits	44502201	CID LINES NV/SA		
OPPTS 830.1800	Enforcement Analytical Method	44502201	CID LINES NV/SA		
OPPTS 830.6302	Color	See file jacket	CID LINES NV/SA		
OPPTS 830.6303	Physical State	See file jacket	CID LINES NV/SA		
OPPTS 830.6304	Odor	See file jacket	CID LINES NV/SA		
OPPTS 830.6313	Stability to normal and elevated temps, metals, ions	N/A	CID LINES NV/SA		[2]

Signature	Name and Title	Date
	Sally Hayes, Agent CID LINES NV/SA	July 30, 2010

[1] Product is not produced using an integrated formulation system.
[2] N/A: Product is an EUP.

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DATA MATRIX

Date July 30, 2010	EPA Reg No./File Symbol 71355-1	Page 2 of 8
Applicant's/Registrant's Name & Address CID LINES NV/SA Waterpoorstraat 2, 8900 IEPER, BELGIUM	Product VIROCID	
Ingredient: Alkyl* dimethylbenzyl ammonium chloride (50% C_{14}, 40% C_{12}, 10% C_{16}); Didecyl dimethyl ammonium chloride; Glutaraldehyde		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.6314	Oxidation/Reduction: chemical incompatibility	See file jacket	CID LINES NV/SA		
OPPTS 830.6315	Flammability	See file jacket	CID LINES NV/SA		
OPPTS 830.6316	Explodability	N/A	CID LINES NV/SA		[3]
OPPTS 830.6317	Storage Stability	See file jacket	CID LINES NV/SA		
OPPTS 830.6319	Miscibility	See file jacket	CID LINES NV/SA		
OPPTS 830.6320	Corrosion Characteristics	See file jacket	CID LINES NV/SA		
OPPTS 830.6321	Dielectric Breakdown Voltage	N/A	CID LINES NV/SA		[4]
OPPTS 830.7000	pH	See file jacket	CID LINES NV/SA		
OPPTS 830.7100	Viscosity	See file jacket	CID LINES NV/SA		
OPPTS 830.7200	Melting Point/Melting Range	N/A	CID LINES NV/SA		[5]
OPPTS 830.7220	Boiling Point/Boiling Range	N/A	CID LINES NV/SA		[5]
OPPTS 830.7300	Density / Relative Density / Bulk Density	See file jacket	CID LINES NV/SA		

Signature	Name and Title	Date
Sally Hayes	Sally Hayes, Agent CID LINES NV/SA	July 30, 2010

[3] N/A: Product does not include ingredients that are potentially explosive.
[4] N/A: Product is not for use in/on/around electrical equipment.
[5] N/A: Product is an EUP.

Form Approved OMB No. 2070-0060

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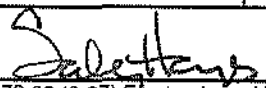
DATA MATRIX

Date July 30, 2010	EPA Reg No./File Symbol 71355-1	Page 3 of 8
Applicant's/Registrant's Name & Address CID LINES NV/SA Waterpoorstraat 2, 8900 IEPER, BELGIUM	Product VIROCID	
Ingredient: Alkyl* dimethylbenzyl ammonium chloride (50% C_{14}, 40% C_{12}, 10% C_{16}); Didecyl dimethyl ammonium chloride; Glutaraldehyde		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.7370	Dissociation Constant	n/a			[6]
OPPTS 830.7520	Particle Size, Fiber Strength, Diameter Distribution	n/a			[6]
OPPTS 830.7550	Particle Coefficient (n-Oct/H2O) shake flask	n/a			[6]
OPPTS 830.7560	Particle Coefficient (n-Oct/H2O) generator column	n/a			[6]
OPPTS 830.7570	Particle Coefficient (n-Oct/H2O) estimation by liquid	n/a			[6]
OPPTS 830.7840	Water Solubility: column elution/shake flask method	n/a			[6]
OPPTS 830.7860	Water Solubility: generator column method	n/a			[6]
OPPTS 830.7950	Vapor Pressure	n/a			[6]
OPPTS 870.1100	Acute Oral Toxicity	45061801	CID LINES NV/SA		
OPPTS 870.1200	Acute Dermal Toxicity	See file jacket	CID LINES NV/SA		
OPPTS 870.1300	Acute Inhalation Toxicity	See file jacket	CID LINES NV/SA		
OPPTS 870.2400	Acute Eye Irritation	See file jacket	CID LINES NV/SA		
OPPTS 870.2500	Acute Dermal Irritation	See file jacket	CID LINES NV/SA		
OPPTS 870.2600	Skin Sensitization	44481802	CID LINES NV/SA		

Signature	Name and Title	Date
	Sally Hayes, Agent CID LINES NV/SA	July 30, 2010

[6] N/A: Product is an EUP from registered active source.

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date July 30, 2010	EPA Reg No./File Symbol 71355-1	Page 4 of 8
Applicant's/Registrant's Name & Address CID LINES NV/SA Vaterpoorstraat 2, 8900 IEPER, BELGIUM	Product VIROCID	

Ingredient: Alkyl* dimethylbenzyl ammonium chloride (50% C_{14}, 40% C_{12}, 10% C_{16}); Didecyl dimethyl ammonium chloride; Glutaraldehyde

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Guideline 91-2	European Suspension Test – *Staphylococcus aureus* (ATCC 6538)	44481801	CID LINES NV/SA		
Guideline 91-2	European Suspension Test – *Streptococcus faecium* (DVG 8582)	44481801	CID LINES NV/SA		
Guideline 91-2	European Suspension Test – *Pseudomonas aeruginosa* (ATCC 15442)	44481801	CID LINES NV/SA		
Guideline 91-2	European Suspension Test – *Proteus mirabilis* (ATCC 14153)	44481801	CID LINES NV/SA		
Guideline 91-2	European Suspension Test – *Escherichia coli* (ATCC 10536)	44481801	CID LINES NV/SA		
Guideline 91-2	European Suspension Test – *Mycobacterium smegmatis* (CNCM 7326)	44481801	CID LINES NV/SA		
Guideline 91-2	European Suspension Test – *Saccharomyces cerevisiae* (ATCC 9763)	44481801	CID LINES NV/SA		
Guideline 91-2	European Suspension Test – *Candida albicans* (ATCC 10231)	44481801	CID LINES NV/SA		
Guideline 91-2	Virucidal Effectiveness Test – Infectious Bursal Disease Virus (SPAFAS Strain 2512)	44869901	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test – *Staphylococcus aureus* (ATCC 6538)	44900201	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test – *Salmonella choleraesuis* (ATCC 10708)	44900201	CID LINES NV/SA		

Signature	Name and Title	Date
	Sally Hayes, Agent CID LINES NV/SA	July 30, 2010

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date July 30, 2010	EPA Reg No./File Symbol 71355-1	Page 5 of 8
Applicant's/Registrant's Name & Address CID LINES NV/SA Vaterpoorstraat 2, 8900 IEPER, BELGIUM	Product VIROCID	

Ingredient: Alkyl* dimethylbenzyl ammonium chloride (50% C_{14}, 40% C_{12}, 10% C_{16}); Didecyl dimethyl ammonium chloride; Glutaraldehyde

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Guideline 91-2	AOAC Use Dilution Test – *Pseudomonas aeruginosa* (ATCC 15442)	44900201	CID LINES NV/SA		
Guideline 91-2	AOAC Fungicidal Effectiveness Test – *Trichophyton mentagrophytes* (ATCC 9533)	44900202	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test – *Staphylococcus aureus* (ATCC 6538)	45770001	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test – *Salmonella choleraesuis* (ATCC 10708)	45770001	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test – *Pseudomonas aeruginosa* (ATCC 15442)	45770001	CID LINES NV/SA		
Guideline 91-2	Virucidal Effectiveness Test – Porcine circovirus type II (PCV, PT-1 cell)	45919001	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test – *Bordetella avium* (ATCC 35086)	46049901	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test – *Campylobacter jejuni* (ATCC 33560)	46049901	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test – *Corynebacterium pseudotuberculosis* (ATCC 19410)	46049901	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test – *Haemophilis paragallinarum* (ATCC 29975)	46049901	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test – *Klebsiella pneumoniae* (ATCC 13883)	46049901	CID LINES NV/SA		

Signature	Name and Title	Date
Sally Hayes	Sally Hayes, Agent CID LINES NV/SA	July 30, 2010

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Date July 30, 2010	EPA Reg No./File Symbol 71355-1	Page 6 of 8
Applicant's/Registrant's Name & Address ID LINES NV/SA Waterpoorstraat 2, 8900 IEPER, BELGIUM	Product VIROCID	
Ingredient: Alkyl* dimethylbenzyl ammonium chloride (50% C_{14}, 40% C_{12}, 10% C_{16}); Didecyl dimethyl ammonium chloride; Glutaraldehyde		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Guideline 91-2	AOAC Use Dilution Test – *Listeria monocytogenes* (ATCC 19115)	46049901	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test – *Mycoplasma gallisepticum* (ATCC 19610)	46049901	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test – *Mycoplasma synoviae* (ATCC 25204)	46049901	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test – *Orinthobacterium rhinotracheale* (ATCC 51463)	46049901	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test – *Pasturella multocida* (ATCC 6529)	46049901	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test – *Salmonella enteritidis* (ATCC 13076)	46049901	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test – *Salmonella pullorum* (ATCC 9120)	46049901	CID LINES NV/SA		
Guideline 91	AOAC Use Dilution Test – *Aspergillus fumigates* (ATCC 10894)	46049902	CID LINES NV/SA		
Guideline 91	AOAC Use Dilution Test – *Fusarium dimerum* (ATCC 16553)	46049902	CID LINES NV/SA		
Guideline 91	AOAC Use Dilution Test – *Penicillium expansum* (ATCC 7861)	46049902	CID LINES NV/SA		
Guideline 91-2	Virucidal Effectiveness Test – Porcine circovirus type II (PT-1 cell)	46341401	CID LINES NV/SA		

Signature	Name and Title	Date
	Sally Hayes, Agent CID LINES NV/SA	July 30, 2010

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date July 30, 2010	EPA Reg No./File Symbol 71355-1	Page 7 of 8
Applicant's/Registrant's Name & Address CID LINES NV/SA Waterpoorstraat 2, 8900 IEPER, BELGIUM	Product VIROCID	

Ingredient: Alkyl* dimethylbenzyl ammonium chloride (50% C_{14}, 40% C_{12}, 10% C_{16}); Didecyl dimethyl ammonium chloride; Glutaraldehyde

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Guideline 91-2	Virucidal Effectiveness Test – Newcastle disease virus (SPAFAS)	46410601	CID LINES NV/SA		
Guideline 91-2	Virucidal Effectiveness Test – Marek's disease virus (SPAFAS)	46410602	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test – *Mycoplasma hyopneumoniae* (ATCC 25934)	46410603	CID LINES NV/SA		
Guideline 91-2	Virucidal Effectiveness Test – Avian infectious laryngotracheitis virus (Charles River Laboratories)	46410604	CID LINES NV/SA		
Guideline 91-2	Virucidal Effectiveness Test – Porcine respiratory and reproductive syndrome virus (Arko Laboratories)	46410605	CID LINES NV/SA		
Guideline 91-2	Virucidal Effectiveness Test – Avian reovirus (SPAFAS)	46410607	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test Supplemental Data – *Streptococcus suis* (ATCC 43765)	46410608	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test Supplemental Data – *Salmonella typhisuis* (ATCC 8321)	46410608	CID LINES NV/SA		
Guideline 91-2	AOAC Use Dilution Test Supplemental Data – *Escherichia coli* (ATCC 11229)	46410608	CID LINES NV/SA		
Guideline 91-2	Virucidal Effectiveness Test – Pseudorabies virus (American BioResearch Laboratories)	46410609	CID LINES NV/SA		
Guideline 91-2	Virucidal Effectiveness Test – Avian Influenza virus (Turkey/Wis/66 strain (H9N2))	46442601	CID LINES NV/SA		

Signature	Name and Title	Date
Sally Hayes	Sally Hayes, Agent CID LINES NV/SA	July 30, 2010

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date July 30, 2010	EPA Reg No./File Symbol 71355-1	Page 8 of 8
Applicant's/Registrant's Name & Address CID LINES NV/SA aterpoorstraat 2, 8900 IEPER, BELGIUM	Product VIROCID	

Ingredient: Alkyl* dimethylbenzyl ammonium chloride (50% C_{14}, 40% C_{12}, 10% C_{16}); Didecyl dimethyl ammonium chloride; Glutaraldehyde

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Guideline 91-2	Virucidal Effectiveness Test – Human Influenza A virus (H1N1)(ATCC VR-1469)	To be assigned	CID LINES NV/SA		
Guideline 91-2	Virucidal Effectiveness Test – Swine Influenza A virus (H1N1)(ATCC VR-333)	To be assigned	CID LINES NV/SA		

Signature	Name and Title	Date
Sally Hayes	Sally Hayes, Agent CID LINES NV/SA	July 30, 2010

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
71355-1	07/30/10	071355-00001.2010730.Amend.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature

07/30/10
Date

Sally Hayes

Name (typed)

Agent

Title

There is an **ELECTRONIC LABEL** for this action

You can use Acrobat to compare the e-label to the previous version (and find the changes). You can also use Acrobat to mark-up the e-label with your comments.

If e-label was submitted via

CD-ROM with paper application

then you will find e-label in

Electronic Label Library

If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the Front End.

or

If e-label was submitted via

XML E-Submission (no paper)

then you will find e-label in

Documentum

See overview of processing e-labels on other side of this sheet.
If you have any questions on e-labels, please contact one of your division e-label experts:

AD	Willie Abney	308-1689
	Renae Whitaker	308-7003
	Tracy Lantz	308-6415
BPPD		
RD	Tom Harris	308-9423

PROCESSING ELECTRONIC LABELS

(rev. 1/5/09, tch)

If e-label submitted via XML e-submission (not on CD-ROM), you may wish to find e-label in Documentum, save e-label to "My Documents", add e-label to ELL, start below at step 5.

Initial E-Label per application (on CD-ROM with paper via ITRMD)

1 ITRMD receives paper submission w/ e-label on CD

2 Tracking record added to OPPIN

3 ITRMD adds e-label to ELL

4 ITRMD sends paper submission to AD/BPPD/RD

5 Connect ELL record with OPPIN S#

in-process

6 Save copy of e-label from ELL to My Documents

7 Review label

(if acceptable, skip to step 20)

8 Add comments to e-label

(save; add "with comments" to filename

9 Print annotated e-label

(use "Print with Filename")

review

10 Send annotated e-label to registrant via email

(also send "How To Print")

11 File print of annotated e-label and email in jacket

12 Add annotated e-label to ELL

13 Close submission in OPPIN

out-process

Resubmission (via email to staffer or PM)

14 Receive email submission w/ e-label attached

15 Add tracking record to OPPIN

16 Add e-label to ELL

17 Connect ELL record with OPPIN S#

in-process

18 Save copy of e-labels (old & new) from ELL to My Documents

19 Compare old and new labels with Acrobat

(if revisions needed repeat steps 8-19)

review

20 Print e-label, stamp, write cover letter

(use "Print with Filename")

21 Mail stamped label & cover letter to registrant

22 File stamped label & cover letter in jacket

23 Add cover letter to ELL

(mandatory if accepted with comments)

24 Close submission in OPPIN

out-process

process - big picture

1- create OPPIN tracking
2- put label in ELL; link to S#
3- save ELL label to MyDocuments
4- compare / comment
5- outprocess

techniques to know

- filename for e-labels
- "print with filename"
- compare / comment
- printing with comments

Memorandum

Date: 08 / 05 / 10

To: PM 31, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☑ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

SRC
Scientific & Regulatory
Consultants, Inc.

July 30, 2010

Velma Noble, PM 31
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

SUBJECT: VIROCID
EPA Reg. No. 71355-1

Dear Velma,

On behalf of CID LINES NV/SA is an amendment with data for Virocid. This amendment is a PRIA action code A570 which is assigned a PRIA fee of $3308 and a 4 month review time. A copy of the confirmation of payment via www.pay.gov is attached.

The purpose of the submission is to:

- Add new claims for Human Influenza A virus (H1N1) and Swine Influenza A virus (H1N1). (See Volumes 3 – 4.)
- Add data previously rejected[1] to support
  - *Mycaplasma gallisepticum*[2],
  - *Mycoplosma synoviae*,
  - *Bordetella avium*,
  - *Klebsiella pneumoniae*,
  - *Ornithobacterium rhinotracheale*,
  - *Salmonella enterica (formerly S. enteritidis)*,
  - *Salmonella enterica (formerly S. cholerasuis, serotype typhisuis)*
  - *Salmonella enterica (formerly S. pullorum)*,
  - *Campylobacter jejuni*,
  - *Corynebacterium pseudotuberculosis*,
  - *Avibacterium paragellinarum (formerly H. paragallinarum)*,
  - *Listeria monocytogenes*,
  - *Fusarium dimerum*, and
  - *Pencillium expansum*

[1] The studies for these organisms were assigned MRID 46049901 and 460499D2. Rationale for accepting this data was provided to Tajah Black prior to filing this submission. Volume 2 of this submission provides justification for accepting this data.

[2] Strain designates (e.g. ATCC) are provided on enclosed data matrix.

P.O. Box 1014
Columbia City, IN 46725
www.srcconsultants.com
Phone: 260-244-6270
Fax: 260-244-6273

- Upgraded the
  - first aid statements, to comply with PR Notice 2001-1,
  - precautionary statements to comply with the Labeling Review Manual Chapter 8, and
  - storage and disposal language to reflect the Container and Containment Review per PR Notice 2007-4.

Enclosed are 5 copies of labeling with the changes and deletions reflected. An electronic label named "071355-00001.2010728.Amend.pdf" is attached which incorporates all changes in proper electronic label format.

The CSF has been updated to reflect a change in ownership of the registered active ingredient, glutaraldehyde. [redacted] is now under the ownership of [redacted] requiring a change in the EPA registered active number from [redacted] to [redacted]. In addition, the [redacted]r listed in Column 13 was corrected to reflect the total product weight as 100% by weight. This replaces the CSF dated 06/10/98.

Please contact me at (260) 244-6270 or shayes@srcconsultants.com if you have any questions regarding this submission.

Sincerely,

Sally Hayes
Agent, CID LINES NV/SA

cc: A. Francois, CID LINES

VIROCID

EPA Registration No: 71355-1

TRANSMITTAL DOCUMENT

1. Name and address of submitter:
   Scientific & Regulatory Consultants, Inc.
   PO Box 1014
   Columbia City, IN 46725

   AGENT FOR:
   CID LINES NV/SA
   Waterpoortstraat 2
   B 8900 IEPER BELGIUM

2. Regulatory action in support of which this package is submitted:
   AMENDMENT: PRIA Code A570, PRIA fee $3308

3. Transmittal date:
   July 30, 2010

4. Vol. 1 Administrative materials:
   A) Cover letter
   B) Copy of Agent Authorization
   C) Copy of PRIA II payment ($3308 for A570 Initial Registration)
   D) Application
   E) Certification with Respect to Citation of Data
   F) Data Matrix
   G) Formulator's Exemption Statement
   H) CSF dated 06/10/98
   I) 2 copies of revised CSF dated 07/28/10
   J) 1 copy of label with changes highlighted and deletions shown
   K) 5 copies of label without highlighting or deletions
   L) Electronic label 071355-00001.20100728.Amend.pdf

5. Vol. 2 Efficacy

48174201 A) Efficacy Discussion

6. Vol. 3 Efficacy

48174202 A) Guideline 91-2 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Human Influenza A (H1N1) (A07937)

7. Vol. 4 Efficacy

48174203 A) Guideline 91-2 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Swine Influenza A (H1N1) (A07938)

Company Official:	Sally Hayes
Company Name:	Agent for CID LINES NV/SA
Company Contact:	Sally Hayes Phone: 260-244-6270 E-mail: shayes@srcconsultants.com

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 4, 2010

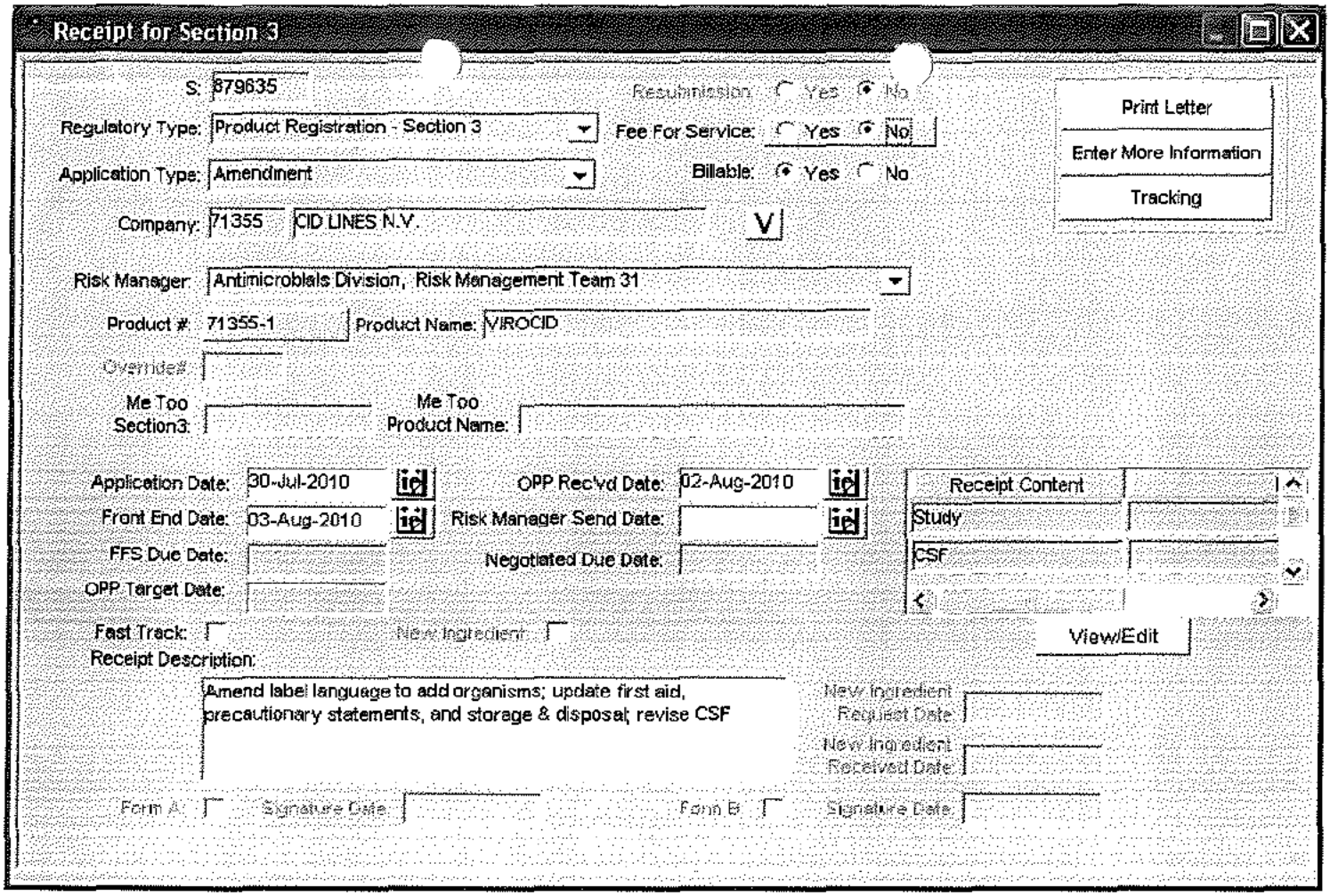
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SCIENTIFIC & REGULATORY CONSULTANTS INC.
CID LINES N.V.
102 1/2 S. CHAUNCEY ST., PO Box 1014
COLUMBIA CITY, IN 46725-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 02-AUG-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.


Receipt for Section 3
S: 879635
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Print Letter
Enter More Information
Tracking
Company: 71355 CID LINES N.V.
Risk Manager: Antimicrobials Division, Risk Management Team 31
Product #: 71355-1
Product Name: VIROCID
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 30-Jul-2010
OPP Recvd Date: 02-Aug-2010
Front End Date: 03-Aug-2010
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Amend label language to add organisms; update first aid, precautionary statements, and storage & disposal; revise CSF
New Ingredient Request Date:
New Ingredient Received Date:
Form A: Signature Date:
Form B: Signature Date:

VIROCID

EPA Registration No: 71355-1

TRANSMITTAL DOCUMENT

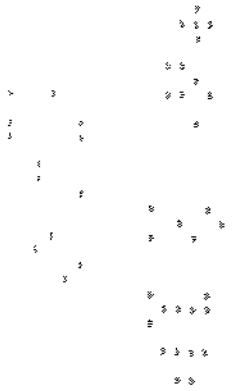
1. Name and address of submitter:
   Scientific & Regulatory Consultants, Inc.
   PO Box 1014
   Columbia City, IN 46725

   AGENT FOR:
   CID LINES NV/SA
   Waterpoortstraat 2
   B 8900 IEPER BELGIUM

2. Regulatory action in support of which this package is submitted:
   AMENDMENT: PRIA Code AS70, PRIA fee $3308

3. Transmittal date:
   July 30, 2010

4. Vol. 1 Administrative materials:
   A) Cover letter
   B) Copy of Agent Authorization
   C) Copy of PRIA II payment ($3308 for AS70 Initial Registration)
   D) Application
   E) Certification with Respect to Citation of Data
   F) Data Matrix
   G) Formulator's Exemption Statement
   H) CSF dated 06/10/98
   I) 2 copies of revised CSF dated 07/28/10
   J) 1 copy of label with changes highlighted and deletions shown
   K) 5 copies of label without highlighting or deletions
   L) Electronic label 071355-00001.20100728.Amend.pdf



5. Vol. 2 Efficacy
   A) Efficacy Discussion

6. Vol. 3 Efficacy
   A) Guideline 91-2 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Human Influenza A (H1N1) (A07937)

7. Vol. 4 Efficacy
   A) Guideline 91-2 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Swine Influenza A (H1N1) (A07938)

Company Official:	Sally Hayes
Company Name:	Agent for CID LINES NV/SA
Company Contact:	Sally Hayes Phone: 260-244-6270 E-mail: shayes@srcconsultants.com

Please read instructions on reverse before completing form. Form Approved, OMB No. 2070-0060, Approval expires 5-31-98

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
71355-1	V. Noble	☑ None ☐ Restricted
4. Company/Product (Name)	PM #	
VIROCID	31	

5. Name and Address of Applicant (Include ZIP Code)

Cid Lines nv/sa,
Waterpoortstraaat 2
B 8900 Ieper, Belgium

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☑ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

PRIA action EPA No. A570, Amendment, non-fast track, PRIA fee $3,308, review time 4 months.
Amend label language to add organisms; update first aid, precautionary statements, and storage & disposal; revise CSF.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No		☐ Yes ☐ No		☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
***Certification must be submitted**	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Label accompanying product

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Person *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Sally Hayes	Agent, CID LINES NV/SA	260-244-6270

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	
Sally Hayes	Agent, CID LINES NV/SA	
5. Typed Name	5. Date	
Sally Hayes	July 30, 2010	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy